BELINDA L. DREISCH and
BURTON J. DREISCH
2605 Greenspring Avenue
Joppa, MD 21085

Plaintiffs

v.

BOX HILL SURGERY CENTER, LLC
100 Walter Ward Blvd.
Suite B2
Abingdon, MD 21009

Serve on:
L. Stephen Hess, Esq.
26th Floor
2100 East Pratt St.
Baltimore, MD 21202

and

RITU T. BHAMBHANI, M.D.
496 Rutland Dr.
Fallston, MD 21047

Serve on:
Ritu T. Bhambhani, M.D.
496 Rutland Dr.
Fallston, MD 21047

and

RITU T. BHAMBHANI, M.D., LLC
496 Rutland Dr.
Fallston, MD 21047

Serve On:
Resident Agent:
Ritu T. Bhambhani, M.D.
496 Rutland Dr.
Fallston, MD 21047

and

*

IN THE

CIRCUIT COURT

OF MARYLAND

FOR BALTIMORE COUNTY

CASE NO: _____

AMERIDOSE, LLC *
205 Flanders Road *
Westborough, MA 01581 *
*
Serve on: *
Registered Agent *
Gregory Conigliaro *
205 Flanders Road *
Westborough, MA 01581 *
*
and *
*
UNIFIRST CORPORATION, *
15 Olympia Avenue *
Woburn, MA 01801 *
*
Serve on: *
Registered Agent *
The Prentice-Hall Corporation System, M *
7 Saint Paul Street, Suite 1660 *
Baltimore, MD 21202 *
*
Defendants *
* *

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW the Plaintiffs, Belinda L. Driesch and Burton J. Dreisch by and through their attorneys Peter G. Angelos, Patricia J. Kasputys, Sharon L. Houston, and the Law Offices of Peter G. Angelos, P.C., and hereby sue Defendants, Box Hill Surgery Center, LLC, a Maryland limited liability company, Ritu T. Bhambhani, M.D., Ritu T. Bhambhani, M.D., LLC, a Maryland limited liability company, Ameridose, LLC, a Massachusetts limited liability company, and UniFirst Corporation, a Massachusetts corporation who does business in Baltimore County, Maryland, and allege:

SUMMARY OF PLAINTIFFS' ALLEGATIONS

1. This is an action for damages suffered by Belinda L. Dreisch, (hereinafter "Plaintiff," individually) and her husband Burton J. Dreisch, as a direct and proximate result of Defendants' wrongful conduct in connection with the compounding, preparing, designing, manufacturing, producing, promoting, selling, distributing, placing in the stream of commerce, selecting, acquiring and/or administering what turned out to be a contaminated steroid medication, methylprednisolone acetate (" MPA"), that Defendants Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC purchased from New England Compounding Center ("NECC") and injected into Plaintiff Belinda Dreisch's body. Despite what these Defendants knew or should have known concerning NECC, they chose to purchase the MPA from NECC, an unaccredited, unsafe compounding pharmacy that: produced these drugs in the same complex as a waste facility, produced the drugs in bulk batches, did not properly sterilize the drugs, did not operate with adequate quality control measures, did not operate in a sterile environment, did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution, did not comply with the United States Pharmacopeial National Formulary ("USP-NF") standards, and violated provisions of Maryland and Massachusetts law designed to protect citizens from substandard and adulterated prescription drugs. As a result of the contaminated MPA being sold by Defendants Box Hill Surgery Center, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC to Plaintiff and injected into Plaintiff's body, Plaintiff contracted fungal meningitis, suffered, continues to suffer, and will continue to suffer, serious bodily injury, and has incurred, continues to incur, and will continue to incur, medical expenses and other economic losses resulting from her injuries, complications and residual medical conditions.

The amount in controversy exceeds the statutory limits for the filing of these claims.

THE PARTIES

2. At all times relevant herein, Plaintiffs Belinda and Burton Dreisch were residents and citizens of Harford County, Maryland. They have been married to each other for thirty-three years, have a nineteen year old daughter and a twenty-five year old son. Belinda Dreisch is 57 years old and worked as a rural letter carrier for 23 years.

3. Defendant Box Hill Surgery Center, LLC, (hereinafter "Box Hill Surgery Center") is a Maryland company with its principal place of business at 100 Walter Ward Blvd., Suite B2, Abingdon, Maryland 21009. At all times relevant herein, Defendant Box Hill Surgery Center was regularly and systematically doing business in Maryland.

4. On information and belief, Defendants Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC, (hereinafter "Dr. Bhambhani") is a Maryland licensed physician and a limited liability company, respectively. Dr. Bhambhani resides at 496 Rutland Drive, Fallston, Maryland 21047. Dr. Bhambhani is board certified in pain medicine and anesthesiology. Her principal place of business is the Box Hill Surgery Center located at 100 Walter Ward Blvd., Suite B2, Abingdon, Maryland 21009, where she is the Medical Director. At all times relevant herein, Defendants Dr. Bhambhani and Ritu T. Bhambhani, M.D., LLC, were regularly and systematically doing business in Maryland.

5. Defendant Ameridose, LLC (hereinafter "Ameridose"), is a Massachusetts limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business located at 205 Flanders Road, Westborough, MA, 01581, formerly of 701 Waverly Street, Framingham, MA. Defendant Ameridose is a sister company to New England Compounding Pharmacy, INC, d/b/a New England Compounding Center (NECC),

a Massachusetts corporation. Ameridose is owned by the same individuals as NECC and currently, or have previously, utilized the same facilities and resources for their business. At all times relevant to this action, Defendant Ameridose manufactured and sold drug products. It has been reported that many employees did not know if they were employees of Ameridose or NECC. Ameridose has been closed since October 10, 2012. Authorities are conducting an ongoing investigation of its facilities. The managers of Ameridose are Gregory Conigliaro and Barry Cadden.

6. Defendant UniFirst Corporation is a corporation duly organized and existing under and by virtue of the laws of the Commonwealth of Massachusetts, with its principal place of business located at 15 Olympia Avenue, Woburn, MA 01801. It may also do business as UniClean Cleanroom Services, and shall be referred to as "UniFirst." UniClean is a division of UniFirst. UniFirst's corporate mission is to be recognized as the quality leader in the cleaning and garment industry. UniFirst also represents that its services will "improve the safety and cleanliness" of a business facility when hired to perform services there. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs. Upon information and belief, UniFirst does business in Maryland and derives substantial revenue from services performed in the State.

JURISDICTION AND VENUE

7. Jurisdiction is proper in Maryland because Defendants transact business or services in the State of Maryland and caused tortious injury by an act in the State of Maryland that caused harm to a Maryland citizen. Md. Code (1974, 2006 Repl. Vol., 2011 Supp.) Courts and Judicial Proceedings Article ("CJ") §6-103.

8. Venue for this action is proper in the Circuit Court for Baltimore County, Maryland pursuant to Maryland Annotated Code, Courts and Judicial Proceedings Article, §6-201that allows for the Defendants to be sued in any county in which any one of them could be sued because of the fact that there is no single venue applicable to all Defendants due to the out of state residency status of some of the corporate Defendants and the location or carrying on of business of one of the Defendants in Baltimore County. Defendant UniFirst Corporation carries on business in Baltimore County at 8820 Yellow Brick Road, Rosedale, Maryland 21237.

NECC's Chapter 11 Bankruptcy Proceeding:

9. On December 21, 2012, NECC filed a petition for bankruptcy protection under Chapter 11 of the Bankruptcy Code which is pending and captioned as *In re: New England Compounding Pharmacy, Inc., Debtor,* United States Bankruptcy Court for the District of Massachusetts Case No. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

10. This case is related to NECC's Bankruptcy case because the prosecution and/or outcome of the proceeding could have an effect on the bankruptcy estate.

11. Adversary proceedings seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against several NECC Related Parties.

FACTUAL BACKGROUND

History of Conigliaro Family Businesses, including New England Compounding Center ("NECC").

Conigliaro Industries' Recycling Plant:

12. In 1990, Gregory Conigliaro opened Conigliaro Engineering in an old industrial

building on Waverly Street in Framingham, Massachusetts. In 1991, the company incorporated under the new name Conigliaro Industries, Inc. and began recycling plastic, metal, glass, and paper. It made money by converting detergent bottles into recycling bins, molded Styrofoam lunch trays into flower pots, and plastic computer casings into pothole filler.

13. Early on, Gregory Conigliaro branched out into real estate, starting GDC Holdings Inc. and GDC Properties Management LLC.

14. In April 2003, Conigliaro Industries opened the first U.S. commercial plant that shreds and recycles mattresses, including polyurethane foam parts. The mattress recycling operation was planned and developed by Tony Conigliaro, the Vice President of Engineering and Gregory's father. The company built a 2,500 square foot mattress shredding facility located next to its 90,000 square foot plant on a seven acre parcel in Framingham. The company also earmarked another 5,000 square feet of its main factory space for the venture and utilized its 30 docks for the operation.

15. Old used mattresses from schools, prisons, and hospitals are put through a giant shredder that separates the polyurethane foam from the springs and wood frame and bales the foam. Gregory Conigliaro claimed that the company (Nationwide Foam, Inc., 703 Waverly Street, Framingham, Massachusetts) could recycle mattresses at the rate of one each minute.

16. Today, Conigliaro Industries touts itself as a pioneer in the field of "Total Recycling" and recycles over 150 different materials, including rubber, plastics, and metal. The business operates out of an 88,000 square foot facility located at 701 Waverly Street, in the large Framingham complex owned by Gregory Conigliaro's real estate companies, GDC Holdings Inc. and/or GDC Properties Management LLC. The Framingham Board of Health has received a

number of complaints about the mounding trash piles tucked behind the Waverly Street strip mall.

Figure 1: Trash behind 701 Waverly Street[1]

1 "Sterility Found Lacking at Drug Site in Outbreak," N.Y. TIMES (Oct. 23, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0),.

Figure 2: Google Earth image of 701 Waverly St.

New England Compounding Center ("NECC"):

17. In 1998, well after the Conigliaro recycling facility and real estate companies were up and running, the Conigliaro family branched out into pharmaceutical compounding. Gregory Conigliaro's sister, Lisa Conigliaro Cadden, and her husband, Barry Cadden, were both pharmacists. Gregory Conigliaro and Barry Cadden co-founded New England Compounding Pharmacy, Inc., known as New England Compounding Center ("NECC"). NECC opened in the same Waverly Street building that housed the recycling plant and real estate businesses. Its front door is immediately next to the front door to Nationwide Foam.

18. Another Conigliaro brother, Dr. Douglas Conigliaro, was an anesthesiologist with substantial litigation in his past. He allegedly punctured a 64-year-old woman's spine during a

1995 operation to insert a pump to deliver painkillers. The woman became paralyzed and died two years later. The suit ultimately settled for $1 million and Douglas Conigliaro was fined $10,000 by the Florida state medical board.

19. Douglas Conigliaro's wife, Carla Conigliaro initially owned sixty-five percent (65%) of NECC. Carla Conigliaro (a nurse) was originally listed as the company's president. Douglas Conigliaro was personally involved with NECC from the beginning and continued to be involved until NECC shut its doors. Because of his previous legal troubles, he was careful to conceal his involvement. He also ordered others at NECC and the Affiliated Defendants to conceal his involvement.

20. Barry Cadden ran NECC, typically wearing scrubs to work. Cadden held positions as the President, Chief Pharmacist, and Director of NECC.

21. Gregory Conigliaro provided financial advice and usually wore a shirt and tie. Lisa Conigliaro Cadden was a board member and worked as a pharmacist at NECC.

22. According to former employees, Douglas Conigliaro was heavily involved in the day-to-day operations of NECC and Ameridose, though employees were told not to mention his involvement to potential clients or customers.

Medical Sales Management:

23. In or around 2002, the Conigliaros opened another company in the same Framingham building, called Medical Sales Management Inc. ("MSM"). MSM, led by Douglas Conigliaro, provided advertising and marketing services for NECC. As the sales arm for NECC and Ameridose, MSM promoted the compounding business at trade shows across the country, and its sales force aggressively worked the phones, cold-calling new customers and reaching out to existing ones. It also helped manage the company's computer operations.

24. Later, MSM provided the same services to Ameridose.

Ameridose:

25. In 2006, Gregory Conigliaro and Barry Cadden launched Ameridose, LLC ("Ameridose"), originally located in the same Framingham building. Former employees say the Conigliaro family found a new opportunity, selling a much-needed service to hospitals: prefilling syringes and breaking down vats of liquid medications into smaller intravenous bags for individual treatments. Historically, hospitals did much of that work themselves. But new federal regulations required hospitals to go through more elaborate steps to handle sterile preparations, making it more costly and complicated.

26. Unlike NECC, Ameridose has a manufacturing license from the FDA, allowing it to ship medications in bulk without obtaining individual prescriptions.

27. Ameridose would later lease additional office space in Westborough, Massachusetts. This additional space was, in part, to accommodate the growing MSM sales force. Ameridose officially changed its address to the Westborough facility in 2011.

28. In 2008, Ameridose had 50 employees. As of 2012, that number had skyrocketed to 400. Ameridose is also currently under investigation for deficient and harmful product compounding and sterilization practices.

Alaunus Pharmaceutical:

29. In 2009, Gregory Conigliaro and Barry Cadden founded yet another company, Alaunus Pharmaceutical LLC. Alaunus identifies, develops, and markets generic pharmaceutical products to physicians and pharmacies throughout the United States. It has several Abbreviated New Drug Applications on file with the FDA, though apparently no approved products. Alaunus is located at 687 Waverly Street, in the same office park as NECC and the recycling facility.

Figure 3: Waverly Business Center Sign[2]

Background on Compounding Pharmacies

30. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

31. NECC's webpage claimed compounding allows doctors to prescribe prescription drugs that are "no longer manufactured, persistently backordered because of production shortages, not commercially available in the dosage form the patient needs (e.g., preservative free)."

2 "Merging of families fueled business linked to meningitis outbreak," BOSTON GLOBE (Oct. 18, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0).

32. In Massachusetts, compounding pharmacies must have a prescription from an individual patient in order to create a drug.

33. Compounding pharmacies generally follow testing guidelines established by the U.S. Pharmacopeia (USP), a nonprofit private group that develops standards of drug quality. According to an industry group, the International Academy of Compounding Pharmacists, adherence to the USP standards is expected. Some Massachusetts compounding pharmacies, including Microtest Laboratories, typically test more than the number of samples required by the USP standards to confirm sterility.

34. Compounding industry standards were created for pharmacists making small batches of medicines for individuals, not for the commercial production of large batches.

The Risks of Pharmacy Compounding

35. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and the medical community before the subject meningitis outbreak.

36. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."

37. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA

approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

38. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

39. In May 2007, the FDA published an article titled: "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

40. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

41. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP, stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

42. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

Meningitis

43. Meningitis is an infection of the membranes covering the brain and spinal cord (meninges). Primary symptoms include: fever, chills, altered mental status, nausea, vomiting, sensitivity to light (photophobia), severe headache, and neck stiffness. Meningitis is typically diagnosed by lumbar puncture (spinal tap) that collects spinal fluid (cerebrospinal fluid). The fluid is then tested to determine the infection's exact cause for an appropriate course of treatment. When a lumbar puncture is not possible, a diagnosis may be presumed based on the constellation of symptoms. Complications and risks from meningitis include: brain damage, buildup of fluid between the skull and brain (subdural effusion), hearing loss, hydrocephalus, and seizures.

44. Meningitis can be caused by several factors including bacteria, viruses, and fungus. Fungal meningitis is rare and people with weak immune systems are at a higher risk of contraction.

45. Meningitis is an infection that usually spreads through the blood to the spinal cord. It is caused by the introduction of a bacteria, virus, or fungus into the central nervous system or from an infected body site infection next to the central nervous system. Primary symptoms include: fever, altered mental status, nausea, vomiting, sensitivity to light (photophobia), headache, and stiff neck. Death may result from fungal meningitis.

46. The typical incubation period for contracting fungal meningitis from a tainted steroid is one to four weeks after injection, though it can be far longer and symptoms can be mild in nature. As with any variety of meningitis, it is important to perform a lumbar puncture (spinal tap) to collect and test spinal fluid (cerebrospinal fluid) and determine the exact type of fungus for an appropriate course of treatment. Appropriate laboratory tests may vary depending on the type of fungus suspected. Treatment of fungal meningitis typically requires long courses of high dose antifungal medications but treatment length can vary depending on the state of the immune system and type of fungus.

The Outbreak and Its Aftermath

47. On September 21, 2012, the CDC was notified by the Tennessee Department of Health ("TDH") of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

48. On September 24, 2012 the TDH notified the Massachusetts Department of Public Health ("MDPH") about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. These patients all received injections of preservative free MPA, compounded at NECC in Framingham, Massachusetts.

49. In September 2012, the TDH identified nine cases of fungal meningitis following injection of MPA, compounded at NECC. All nine patients had received one or more injections from three lots of MPA (lot numbers 05212012@68, 06292012@26, and 08102012@51).

FDA and MDPH Begin Investigating NECC

50. The MDPH, Board of Registration in Pharmacy, and Bureau of Infectious Disease convened a multi-agency meeting with the TDH, the CDC, the FDA, and NECC. At the demand of MDPH staff, Barry Cadden and Gregory Conigliaro provided documentation of facilities that

received medications from three lots of MPA suspected as linked to the fungal infections. According to those lists, the suspected lots contained 17,676 doses and were distributed to more than 14,000 patients in 23 states.

51. On September 26, 2012 NECC recalled three lots of preservative-free MPA: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013. Approximately 3,000 doses were quarantined or returned through recall. This meant that approximately 14,000 people received contaminated injections. NECC faxed the recall notices to the facilities that had received the contaminated lots beginning on September 26, 2012.

52. On the same day, the MDPH began its investigation of NECC's facility. When MDPH arrived at NECC, investigators found NECC employees cleaning compounding areas and conducting environmental testing. The investigators also detected signs of black contamination in the compounding areas.

53. Before arrival of investigators, NECC had terminated many of its staff. After September 26, 2012, the majority of NECC employees were no longer on site.

54. On October 1, 2012, MDPH and FDA began a joint investigation of NECC. Investigators were shown examples of MPA products that were labeled as patient-specific. But NECC did not have individual prescriptions. Instead, it had lists of patients generated by clinical facilities and provided to NECC to obtain the product. NECC stated that the list of names was considered to be an authorized prescription by the physician. This practice is not in accordance with Massachusetts regulations.

55. MDPH issued a formal Quarantine Notice pursuant to M.G.L. c. 94C §§13 and 189A, and M.G.L. c. 112 §§ 30 and 42A, in accordance with the CDC's epidemiological work.

The Notice directs that all raw materials, all non-sterile and sterile products located at NECC used in the compounding of MPA and all inventory on the premises prepared for dispensing and stored at the pharmacy should be quarantined and not disposed of without MDPH's approval.

56. MDPH and FDA observed visible black particulate matter in sealed vials of purportedly sterile MPA returned to NECC. Inconsistencies in sterilization of processed materials were identified through review of NECC's records. The board voted to obtain a Voluntary Surrender of NECC's license or to initiate action to issue a Temporary Order of Summary Suspension.

NECC Surrenders Its Pharmacy License and Recalls All of Its Products

57. On October 3, 2012, NECC surrendered its pharmacy license. It ceased all production and initiated a recall of all MPA and other drug products prepared for injections in and around the spinal cord (known as intrathecal administration).

58. On October 5, 2012, MDPH and FDA investigators noted visible contaminants in additional sealed recalled vials of MPA. MDPH and FDA issued a nationwide alert to providers and facilities across the country, informing them about the particulate matter.

59. On October 6, 2012, NECC, in conjunction with the investigations by the FDA, CDC, and the Massachusetts Board of Registration in Pharmacy, recalled all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts "due to the potential risk of contamination."

60. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

FDA and Massachusetts Board of Pharmacy Findings

61. MDPH obtained documentary evidence (including photographs), reviewed and obtained copies of NECC Standard Operating Procedures, made observational findings, reviewed and obtained copies of all policies and procedures, reviewed batch records and interviewed NECC staff. The FDA conducted product testing and took environmental samples of various areas of the facility to test for contaminants.

62. From the beginning of their investigation, the MDPH and FDA identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk." The FDA reported that it had detected fungal contamination by microscopic examination of particulate matter taken from a sealed vial of MPA collected from NECC. The FDA also noted that "foreign material" had also been observed in other vials produced by NECC that were collected by FDA during an inspection. FDA further stated that it was in the process of further identifying the fungal contaminant and conducting microbial testing.

MDPH's Preliminary Findings

63. On October 23, 2012, the MDPH released its preliminary investigation findings.

64. NECC distributed two of the recalled lots of MPA (preservative free) 80 MG/ML before receiving results of sterility testing. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were sent out before the final sterility tests results were received. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. At least eleven shipments of product were sent out before the final sterility test results were received. NECC's records claim

that these sterility tests found no contamination, but the MDPH questioned whether NECC's sterility testing methods were adequate.

65. The MDPH observed visible black particulate matter in several recalled sealed vials of MPA from Lot 08102012@51.

66. NECC did not follow either the proper USP 797 autoclaving sterilization procedure or its own standards operating procedures. The MDPH noted NECC's systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

67. MDPH found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license.

68. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

69. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

70. The clean rooms used to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.

71. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area, were not thoroughly cleaned pursuant to USP 797 or pursuant to NECC standard operating procedures. Residual powder was visually observed, which could lead to contamination of compounded medications.

72. "Tacky mats" used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris, in violation of USP 797.

73. A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.

FDA's Initial Findings and Form 483 Report

74. On October 18, 2012, the FDA released definitive laboratory confirmation of the presences of fungal contaminants in sealed vials of MPA in a suspect lot prepared by NECC.

75. On October 26, 2012, the FDA released a copy of the FDA Form 483 issued to NECC. The FDA issues a 483 at the end of an inspection when the investigators believe that they observed conditions or practices that indicate violations of the Food, Drug, and Cosmetic Act or attendant regulations.

76. The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the Clean Room 2 at NECC's Framingham facility.

77. During an October 2, 2012 inspection, the FDA observed that approximately 83 vials of a bin of 321 vials of MPA from Lot #08102012@51 (shipped between August 17, 2012 and September 25, 2012) contained a greenish black foreign matter. Seventeen vials from the same bin contained white filamentous material.

78. The FDA's sterility analysis of a sample confirmed the presence of "viable microbial growth" in all of the 50 vials tested. One vial showed fungal morphological features.

79. The FDA reported that NECC's formula worksheets state that the raw materials used to create their drug products are sterile, NECC's pharmacy director told the FDA that NECC uses non-sterile active pharmaceutical ingredients (API) and non-sterile raw materials to formulate preservative-free MPA, triamcinolone, and other injectable suspensions. The

inspection confirmed that the labeling for the MPA, API, and other raw materials did not indicate that they were sterile.

80. NECC claimed that its "steam autoclave cycle" "sterilized" suspensions formulated with non-sterile materials. The FDA noted that NECC provided no documentation or evidence that this autoclave procedure worked. In fact, the FDA reported tarnish, condensation, and discoloration in the autoclaves. The FDA also observed puddles of water in the base of the autoclave chamber.

81. The FDA also reported that on at least 26 occasions between January 2012 and September 2012, NECC's internal environmental monitoring program recorded bacteria and mold in the clean rooms used to produce "sterile" drug products. This included at least 38 instances where the level of bacteria recorded was above the level where NECC was supposed to take action ("action level" or "action limit") and 18 instances where the level of mold reported was above NECC's action level. According to the FDA's director of manufacturing and product quality, an action limit is a threshold measurement of contamination "above what would typically be seen in a controlled sterile environment." Yet NECC took no action to investigate or correct this bacterial and mold contamination:

> There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.

82. Some of the petri dishes used to grow microbes present in environmental samples taken from windowsills, equipment, furniture, floors and other surfaces were "overflowing" with bacteria or fungi in sheets "very visible to the naked eye." The FDA also reported that samples taken from inside the hoods used for compounding (also inside the ostensibly clean rooms) between January and September 2012 showed at least eight instances of bacterial and/or mold

contamination. NECC did not investigate this contamination, did not identify the types of mold or bacteria growing in their ostensibly sterile hoods, nor investigate the impact of this contamination on any of the purportedly sterile products made in the hoods on the days the samples were taken. "[NECC] has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

83. The FDA also observed that a plastic and mattress recycling facility next door produced dust and other airborne contaminants. NECC's HVAC units on the roof were about 100 feet from the recycling facility. Inside NECC, the FDA observed that dark particulate and white, filamentous substances covered the louvers of an HVAC return located behind the autoclave in the clean room.

84. The FDA also observed that the air-conditioning in the clean rooms was turned off overnight. This is not typical for a clean room, as temperatures need to be kept constant to minimize microbial growth.

85. The FDA also observed that a boiler located within 30 feet of the entrance to one "Prep Room" was leaking water into puddles. The wet floor around the boiler was soiled with thick white debris and thick black granular material.

86. The mat at the entrance of the Prep Room was brown and soiled. In other words, it was filthy.

87. The FDA also observed cloudy discoloration on the barrier facing the ISO 6 Clean Room and metal surfaces of the pass-through in the wall to the ISO 6 Clean Room. The metal ledge within the clean room contained reddish-brown and cloudy substances. And there were "dark, hair like discoloration" along the gasket and crevices located at the bottom edge of

the closed pass-through installed within the wall of the ISO 6 Clean Room. NECC used ISO 6 Clean Room to formulate and fill sterile preparation, including MPA.

The Investigation Grows, Covering Other Drugs and Related Corporate Entities

MDPH Shuts Down Ameridose and Suspends Insiders' Pharmacy Licenses:

88. On October 8, 2012, at the MDPH and FDA's insistence, Barry Cadden, Glenn Chin, and Lisa Cadden, leaders at NECC, agreed to stop practicing as pharmacists until the investigation was complete. On October 10, 2012, MDPH asked Ameridose and Alaunus Pharmaceuticals to cease all operations, including dispensing, manufacturing, or distributing any products. MDPH demanded that Barry Cadden immediately resign as manager, director and from any other management position at NECC, or Ameridose.

FDA Confirms Other NECC Products Are Contaminated:

89. On October 15, 2012, the FDA issued an advisory that a patient may have acquired fungal meningitis from a different steroid injection, triamcinolone acetonide. In addition, the FDA reported a transplant patient with aspergillus funigatus infection who received NECC cardioplegic solution during surgery. MDPH asked Massachusetts providers to contact any patients who received any injectable product, including opthalmis drugs or cardioplegia solutions prepared by NECC after May 21, 2012.

90. On October 18, 2012, the FDA confirmed the presence of fungal contaminates in sealed vials of MPA in a suspect lot prepared by NECC. The FDA also collected samples from sealed vials of completed product at Ameridose.

Board of Pharmacy Revokes Cadden, Chin and Conigliaro Pharmacy Licenses:

91. On October 22, 2012, the Board of Pharmacy and MDPH announced that Barry J.

Cadden, Glenn A. Chin, and Lisa Conigliaro Cadden are prevented from practicing as pharmacists, that it asked all three to surrender their pharmacist licenses immediately, and that if they did not voluntarily comply, their license would be permanently revoked. According to MDPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

FDA and MDPH Investigate Ameridose and Alaunus Pharmaceuticals

92. On October 19, 2012, investigators at MDPH and FDA scrutinized the business practices of Alaunus Pharmaceuticals and the potential for inappropriate distribution of NECC or Ameridose products.

93. On October 31, 2012, Ameridose announced a recall of all of its products. The company sells more than 2,200 drugs in syringes (injectable and oral) and intravenous medicine bags.

94. Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the FDA, said in a telephone interview that the company offered to recall all of its products after federal officials shared the results of their inspection, which found fault with some of its sterility "assurances."

95. On November 1, 2012, the FDA and CDC found bacterial contamination in two other drugs made by NECC, preservative-free betamethasone (a steroid used to help back pain) and cardioplegia solution (used during heart surgery). The FDA found bacteria in three separate batches of betamethasone. Earlier tests had found fungal contamination in the cardioplegia solution. These findings "reinforce the FDA's concern about the lack of sterility in products produced at NECC's compounding facility and serve to underscore that hospitals, clinics, and health care providers should not use any NECC-supplied products."

FDA Confirms Ameridose's Products Are Contaminated:

96. On November 9, 2012, the FDA released a report describing the results of its inspection of the Ameridose facilities at 701 and 705 Flanders Road in Westborough, MA. The dates of inspection included October 10-12, October 15-16, October 18-19, October 22-23, October 26, and November 6-9.

97. The report made 15 observations. Two of these observations were "repeat items" included in an FDA Form 483 report issued to Ameridose on August 6, 2008. Namely, that (1) Ameridose does not test the potency of its final drug products before releasing them for distribution (despite receiving 33 complaints about lack of effect) and (2) Ameridose does not test final units of finished product lots for sterility and the presence of bacterial endotoxin.

98. The FDA observed that Ameridose failed to investigate microbial contamination observed at least fifty three (53) times during sterility testing of stock solutions intended to be used in the manufacture of sterile injectable products, including lots of Fentanyl, Ropivacain, and Morphine. Multiple lots of purportedly sterile injectable drug products were compounded, prepared, sold, and distributed from these contaminated lots.

99. The FDA saw "no documented evidence" to suggest that Ameridose ever conducted a health hazard investigation of these 53 instances of contamination. Ameridose claimed that these sterility failures were attributed to contamination during the sterility testing itself (as opposed to during the manufacture of the product); the FDA noted that there was "no data to support" this claim.

100. Ameridose regularly disregarded sterility test results that were "positive," meaning that test results showed products were contaminated and/or not sterile. Ameridose assumed that any positive result was "inconclusive" or "suspect" and re-ran the test. This re-

testing often revealed more non-sterile units than the original test. Ameridose did nothing to identify the source of the contamination nor subculture the bacteria to determine its identity.

101. In 2012, forty-five (45) environmental microbiological contaminants, bacterial and mold, were found in "critical areas," including instances of employees' presumably uncovered fingers inside on the hoods and controlled manufacturing areas during the manufacture of purportedly sterile drug products. There is no evidence that Ameridose took any steps to assess the potential quality impact of these potential contaminates. On at least one occasion, Ameridose "re-filtered" sterile stock solutions involved in the sterility failure and then released the final drug products for patient use.

102. Ameridose received at least 29 adverse event reports associated with its products. These ranged from reports of low potency, post-partum hemorrhaging, over-sedation, respiratory distress, and lack of effect. Ameridose did not report any of these adverse events to the FDA, as required by law. Instead, Ameridose called these "patient responses" or "non-complaints" and did not investigate or failed to investigate what the FDA called "a trend of complaints."

103. The FDA also observed visible indications of deficient manufacturing conditions. Gowns, eye-protection, and gloves worn by employees were not sterile and were reused multiple times before being sent for cleaning. Ameridose failed to perform environmental monitoring of the hoods used to manufacture products. "Penetrating leaks" were observed in the roof above the clean room; Ameridose used totes to catch the streaming rain water. Walls in a room used to prepare purportedly sterile drug products were cracked, corroded, and covered with a sticky materials. "Brownish structures," "whitish, opaque structures," rust, broken glass, "foreign material" and "thick residues" that were orange, brown, and green were found in and around the

metal hoods used to prepare drug products. All of these hoods were indicated to be "clean and available for processing."

104. Ameridose did not evaluate any alarms reported by their air handling system.

105. Perhaps most disturbingly, the FDA reported insect infestations within 3-10 feet of the controlled area where sterile products were made. And at least one bird flew through an area where sterile finished product is packaged and stored during the FDA's investigation.

Criminal and Congressional Investigations

106. The Department of Justice and the Commonwealth of Massachusetts have announced that they are pursuing criminal investigations of NECC's practices. Other States' Attorney Generals are also pursuing criminal investigations, including Michigan's, the state that has the most reported deaths and illnesses linked to NECC's Contaminated Drugs.

107. The U.S. House of Representatives Energy and Commerce Committee is also investigating the outbreak; in particular, the history of investigations and operation at NECC and other companies Barry Cadden was affiliated with that were at any point involved in the production, sale, and/or distribution of drug products. On October 11, 2012, the Committee wrote to Barry Cadden individually to request that NECC preserve all relevant documents and communications and that NECC make arrangements with Committee staff to testify before the Committee before October 18, 2012. Neither Cadden nor anyone else from NECC made themselves available to brief the committee.

108. On October, 22, 2012, the Committee asked Cadden to provide documents from January 1, 2002 through the present, including:

> All documents containing communications referring to relating to any license or inspection of the NECC, Ameridose, and/or Alaunus that [Cadden] sent or received using a personal email account;

All documents containing communications referring or relating to the scope of business conducted by the NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account;

All documents containing communications referring or relating to any safety and/or quality issue related to any product produced, sold, and/or distributed by NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account.

109. On November 14, 2012, the Committee held a hearing, titled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?" Barry Cadden appeared, but repeatedly asserted his Fifth Amendment right against self-incrimination and did not answer any of the Committee's substantive questions.

NECC files Bankruptcy

110. On December 21, 2012, NECC, facing over 130 lawsuits, filed for Chapter 11 bankruptcy in the US Bankruptcy Court of the District of Massachusetts.

111. Pursuant to 11 U.S. C. § 362(a), all actions against NECC are stayed.

Current Case Counts

112. As of November 3, 2013, the CDC reported 751 cases of fungal meningitis, stroke due to presumed fungal meningitis, or other central nervous system-related infection meeting the outbreak case definition, in addition to paraspinal/spinal joint infections and peripheral joint infections (e.g., knee, hip, shoulder, and elbow). The CDC reported cases in Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. Of these 751 reported cases of fungal meningitis, at least 64 people have died (in nine different states). The CDC estimates that at least 14,000 patients were administered injections from just the three recalled lots of methylprednisolone acetate.

Maryland and Massachusetts Law

113. The Code of Maryland Regulations (hereinafter "COMAR") provides quality of care licensing standards for health care providers and facilities that are licensed by the Office of Health Care Quality. Under Title 10 Department of Health and Mental Hygiene Subtitle 05 Freestanding Ambulatory Care Facilities, 10.05.01.06 (D) Policies and Procedures, the administrator, in consultation with the medical director, shall develop and implement policies and procedures governing the operation of the facility which include at a minimum: ...(8) Infection control for patients and staff; ... E. The administrator shall ensure that all: ...(3) Appropriate personnel implement all policies and procedures as adopted.

114. COMAR 10.05.05.10 Pharmaceutical Services provides: A. The freestanding ambulatory surgical facility shall: (1) Provide drugs and biological under the direction of an authorized prescriber; and (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice. B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.

115. COMAR 10.34.19.08 Batch Preparation states: (A) A pharmacist may prepare batched sterile preparations for future use in limited quantities supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order. (B) Batch preparation of specific compounded sterile preparations is acceptable if the: (1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship and (2) Pharmacy maintains the prescription on file for such preparations dispensed.

116. COMAR 10.34.19.06 (B) states: "The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law:

… (5) The name of the patient; …

117. Massachusetts CMR 721.020 states:

Every prescription written in the Commonwealth must be in a prescription format that conforms to the following requirements:

721.020 (E)(4) name and address of the patient …

118. The Maryland Consumer Protection Act (hereinafter "CPA") establishes minimum standards of conduct in the marketplace to protect consumers. To establish a violation of the CPA, a Plaintiff must prove that the Defendant engaged in unfair and deceptive trade practices in connection with the sale or offer for sale of consumer goods, causing the Plaintiff to sustain injury. *Morris v. Osmose Wood Preserving*, 340 Md. 519, 538-539, 667 A.2d 624 (1995). The deceptive practice must occur in the sale or offer for sale to consumers. A private party suing under the CPA must establish actual injury or loss. *Morris*, 340 Md. At 538.

119. Maryland Courts and Judicial Proceedings §5-405 Sealed container defense in product liability. … (b) Elements of defense to action against product's seller. – It shall be a defense to an action against a seller of a product for …personal injury allegedly caused by defective design or manufacture of a product if the seller establishes that: …The seller in the performance of the duties he performed or while the product was in his possession could not have discovered the defect while exercising reasonable care; … (c) *Defense not available.* – The defense provided in subsection (b) of this section is not available if: (1) The manufacturer is not subject to service of process under the laws of this State or the Maryland Rules; …

FACTUAL ALLEGATIONS

Ameridose

120. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution center to entities of common ownership - currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

121. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

122. On April 11, 2011, Ameridose employee, Michelle Rivers, upon information and belief and at the direction of the NECC principals, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

123. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact "mlord@medicalsalesmgmt.com." Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

124. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

125. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW has reportedly stated: "I didn't think there was any difference [between Ameridose and NECC]."

126. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

UniFirst Corporation

127. UniClean Cleanroom Services ("UniClean") is a division of Defendant UniFirst Corporation. Hereafter the entity shall be referred to as "UniFirst." UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals.

128. UniFirst itself and/or through UniClean, touts its expertise to companies like NECC and Ameridose. UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials Unifirst acknowledges that to reduce these

risks, it is imperative that an effective cleanroom cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

129. At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst itself and/or UniClean, represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

130. UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC or Ameridose has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

131. UniFirst markets its products and services aggressively, and represents that, among other things, "To help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

132. UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012.

133. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each Cleanroom at the NECC facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and thereafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included but were not limited to the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst.

134. UniFirst agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.

135. UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered.

136. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the cleanrooms UniFirst was entrusted to clean in the following ways: (A) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (B) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had

been moved through exterior environments, even though such equipment had not been sanitized or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility; and (C) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

137. UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants - if not eliminated - would expose patients and end use consumers such as Plaintiffs, to contamination of products produced by NECC in its cleanrooms.

138. UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

139. Aspergillus niger was found or brought into in the NECC facility. UniFirst failed to perform the job it was hired to do.

140. As a result of failures and omissions, UniFirst (solely or in concert with NECC) negligently allowed contaminants such as aspergillus into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored.

141. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into the NECC facility, including its anterooms and cleanrooms. UniFirst did not conduct appropriate due diligence to follow its own policies and procedures, and failed to follow NECC policies and procedures when in that facility.

Box Hill Surgery Center and Dr. Bhambhani

142. Plaintiff Belinda Dreisch sought treatment from the Defendant Healthcare Providers.

143. The Defendants and their employees, affiliates, and agents owed Plaintiff numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers and to ensure that the medical treatment, including drugs, that they administered to patients, including Plaintiff, were safe and effective.

144. As part of this medical treatment, the Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiff.

145. Defendants injected MPA directly into Plaintiff's spinal canal so as to enter the central nervous system, bypassing many or all of the body's natural defensive mechanisms.

146. The Defendants knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.

147. The Defendants knew, or should have known, that the MPA they purchased acts as an immune system-suppressing agent, thus weakening the patient's, including Plaintiff's, natural ability to fight off pathogens that could possibly be included in the injection.

148. The Defendants knew, or should have known, the importance of purchasing and administering safe and effective drugs to their patients, including Plaintiff.

149. The Defendants knew, or should have known, that one of the best ways of ensuring that they inject safe and effective drugs directly into the spinal canals and other vulnerable places of their patients was to use only drugs approved by the FDA for the intended form of administration.

150. The use of NECC's drugs administered to the Plaintiffs has not been approved by the FDA.

151. The Defendants knew, or should have known, that NECC's drugs that it administered to the Plaintiffs had not been approved by the FDA.

152. The Defendants knew, or should have known, that another way of ensuring that they administered safe and effective drugs directly into, for example, the spinal canals of their patients, was to purchase such drugs from an FDA-regulated manufacturer.

153. The Defendants knew, or should have known, that NECC was not an FDA approved manufacturer.

154. NECC's un-regulated drugs were used by the Defendants in lieu of commercially available drug products manufactured by FDA-regulated manufacturers.

155. Although NECC operated in Massachusetts, it was also required to comply with the laws of the states of the Defendants, including Maryland.

156. It is a violation of the laws of the State of Maryland to sell compounded drugs in bulk and without a patient-specific prescription. NECC violated these laws.

157. Rather than producing small quantities of its drugs on a per-prescription basis, NECC engaged in the illegal and risky process of producing and marketing very large quantities of its drugs at one time and not per prescription as required by Maryland law.

158. The Defendants knew, or should have known, that NECC engaged in the process of producing and marketing very large quantities of its drugs.

159. Under the law of numerous states, corporations like NECC located outside their states who engage in the wholesale distribution of prescription drugs into their states must register with those states.

160. NECC acted as a wholesale distributor by selling very large quantities of its drugs to the Defendants.

161. The Defendants knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of its drugs to them, without being registered to do so.

162. The Defendants knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in Maryland.

163. NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of the laws of many states, including Maryland.

164. The Defendants knew, or should have known, that NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of state laws.

165. Notwithstanding the foregoing knowledge, the Defendants voluntarily purchased drugs for use on the Plaintiff on a wholesale basis from NECC without prescriptions.

166. It is believed that the Defendants provided patient lists to NECC even though the patients on the lists did not necessarily receive the drug. Often times, the lists provided to NECC by the Defendants included false patient names.

167. By providing a list of names of patients who were not necessarily going to receive the drug, and certainly providing false names, the Defendants conspired with NECC, ignoring patient safety.

168. Under Maryland law, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary).

169. NECC and its pharmacists did not comply with USP-NF standards.

170. The Defendants knew, or should have known, that NECC was not compliant with USP-NF standards.

171. The Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Plaintiff, was to purchase such drugs from an accredited compounding pharmacy or purchase pharmaceuticals directly from pharmaceutical manufacturers regulated by the FDA.

172. NECC is not, and at all relevant times was not, accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organization, such as The Joint Commission, that offer independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

173. The Defendants knew, or should have known, that NECC was not an accredited compounding pharmacy.

174. There are accredited compounding pharmacies throughout the United States, and it is believed, in Maryland, the Defendants' own state, but the Defendants chose not to purchase drugs from them, electing instead to buy drugs from an unaccredited, unregistered wholesale pharmacy for use in treating Plaintiff.

175. The Defendants knew, or should have known, that another way of ensuring that safe and effective steroids are administered to their patients was to purchase drugs which contain preservatives.

176. The hazards, dangers and problems entailed in administering compounded drugs, and especially the use of preservative-free sterile preparations, were well known to the medical profession, including the Defendants, and the subject of many articles and professional guidance documents.

177. NECC produced MPA, and other drugs administered to the Plaintiffs, without preservatives.

178. The Defendants knew, or should have known, that NECC produced drugs they administered to the Plaintiff without preservatives.

179. The Defendants knew or should have known that purchasing and utilizing preservative-free products, as was done here, increased the risk of contamination. Because the vials contained no antimicrobial preservative, there was nothing to inhibit the growth of bacteria and fungus that were introduced into the drugs administered to the Plaintiff by the Defendants.

180. Despite the increased risk of using preservative free drugs, and of purchasing drugs not approved by the FDA, the Defendants purchased the drugs they administered to the Plaintiff from un-accredited NECC for use in the most vulnerable areas of the Plaintiff's body.

181. The Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Plaintiff, was to ensure that such drugs are produced to the highest standards, including in a highly sterile environment.

182. While NECC is not regulated by the FDA, the American Society of Health-System Pharmacists (ASHP) has published *Guidelines on Outsourcing Sterile Compounding Services* (herein after Outsourcing Compounding Guidelines). At all relevant times, the Defendants were subject to the Outsourcing Compounding Guidelines.

183. At all times relevant, the Defendants failed to perform the following due diligence prior to purchasing sterile compounds from NECC, as recommended by the ASHP *Guidelines on Outsourcing Sterile Compounding Services*, including, but not limited to:

a. verify whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

b. determine if NECC was an accredited compounding pharmacy;

c. at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff;

d. determine whether NECC had any product liability lawsuits filed against it for preparations compounded;

e. determine whether there had ever been recalls of any of NECC's compounded preparations;

f. evaluate NECC's standard operating procedures and manuals;

g. evaluate NECC's pharmacist technician training;

h. evaluate NECC's policies and procedures for sterility testing;

i. evaluate examples of batch reports for product being considered for outsourcing;

j. evaluate examples of quality-control reports;

k. obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l. determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

m. evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability;

q. determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; and

t. determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

184. Upon information and belief, had the Defendants followed the recommendations set forth in the Outsourcing Compounding Guidelines, it would have found NECC in the deplorable conditions set forth above, learned of its unsuitable, checkered history, prior reprimands, and problems and complaints related to their practices and products.

185. Despite the importance of the sterile nature of the drugs the Defendants administered to Plaintiffs, NECC's facility and production processes were unsanitary and unsterile, and lacked adequate quality control measures.

186. The Defendants knew, or should have known, that NECC's drugs and production processes were unsanitary and unsterile, and lacked adequate quality control measures.

187. NECC took large quantities of non-sterile ingredients and placed them into an aqueous mixture that then had to be rendered sterile.

188. NECC's process made its drugs unreasonably dangerous, high risk compounds.

189. NECC competed in the medical marketplace on the basis of offering cheaper prices. Upon information and belief, NECC's cheaper pricing was a major factor in the Defendants' decisions to purchase drugs from NECC, as opposed to from other FDA-regulated manufacturers of approved drugs.

190. Despite what the Defendants knew, or should have known, concerning NECC, they chose to purchase the drugs they administered to the Plaintiff from NECC, which was an

unaccredited, unsafe compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches; (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution; (g) did not comply with USP-NF standards; (h) violated several provisions of Maryland law designed to protect its citizens from substandard and adulterated prescription drugs; and (i) contracted with a cleaning company that failed to adequately and non-negligently perform the work it was hired to do.

191. The Defendants failed to inform their patients, including Plaintiff, that they were receiving a drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems as described in the preceding paragraphs.

192. The Defendants failed to inform their patients, including Plaintiff, that they were receiving a drug that was not approved by the FDA. They also failed to inform the Plaintiff that the drugs were obtained via mail order from a pharmacy in Massachusetts that was neither inspected by the FDA nor was accredited by any valid accrediting body. Such information is objectively material information to a reasonable patient's decision to undergo a procedure using such medication.

193. On the contrary, upon information and belief, the Defendants failed to inform its patients, including Plaintiff, that the drugs obtained from NECC and injected into Plaintiffs' spinal canal were not, in fact, the name brand drug produced by a FDA-regulated laboratory and/or a generic drug produced by a FDA-regulated laboratory.

194. At all relevant times, Plaintiff never received a drug produced to the same high quality standards as name brand or generic drugs produced by FDA-regulated manufacturers from the Defendants and was never informed of the Defendants choice to purchase the drugs administered to them from an un-accredited facility like NECC.

195. In connection with the Defendants obtaining NECC's preservative free drugs for its patients, including Plaintiff, the Defendants either failed to take or negligently performed the reasonable and necessary due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's products, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative free drugs for use by the Defendants in procedures on the Plaintiff.

196. At all times and places pertinent to this action, the drugs that the Defendants voluntarily purchased from NECC and then sold and provided to their patients, including Plaintiff, were contaminated with fungus, mold, and/or other contaminants, and, therefore, unsafe and unreasonably dangerous.

197. As a direct and proximate result of the Defendants wrongful conduct, the Plaintiff was administered contaminated products by the Defendants, causing serious injuries to the Plaintiff.

PLAINTIFF SUFFERS DAMAGES CAUSED BY INJECTION OF CONTAMINATED MPA

198. Defendants Box Hill Surgery Center and Ritu T. Bhambhani purchased bulk shipments of MPA from NECC which were sent to them on August 13, 2012, that included 85/ 5ml vials of MPA (PF) 80 mg/ml injectable solution; a shipment sent on September 25, 2012,

that included 300/1 ml vials of MPA (PF) 80mg/ml injectable solution; and a shipment sent on September 25, 2012, that included 50/1 ml vials of MPA (PF) 40mg/ml injectable solution.

199. On May 18, 2012, July 13, 2012, and August 24, 2012, Plaintiff purchased and received injections of MPA from Defendants for the treatment of lumbar degenerative disc disease, lumbar spondylosis, and lumbar radiculopathy/radiculitis.

200. On September 11, 2012, the Plaintiff presented to Upper Chesapeake Medical Center (hereinafter "Upper Chesapeake") Emergency Room (hereinafter "ER") with complaints of excessive vomiting, lower back pain, and generalized headache that was worse in the back of her head and, felt like an ice pick. The Plaintiff was admitted to the hospital the following day with the additional symptoms of chills, photophobia, a sharp, stabbing, continuous headache rated 10/10, and tailbone pain. She advised that her pain management physician had given her an epidural steroid injection approximately two weeks before. Neither Dilaudid nor Morphine resolved her pain. A lumbar puncture was done that showed abnormalities and she was diagnosed and treated for viral meningitis with intravenous (hereinafter "IV") medication.

201. On September 14, 2012, Plaintiff's condition seemed to improve and she was discharged to home to take over-the-counter pain medication. Her final diagnoses was viral meningitis.

202. On September 15, 2012, within hours of being discharged, she returned to Upper Chesapeake ER with severe head and back pain. Dilaudid was given intravenously and her pain subsided. She was discharged in "good condition".

203. On September 16, 2012, her pain returned so she sought treatment at Franklin Square Medical Center (hereinafter "Franklin Square") ER where she was admitted with a diagnosis of "headache and back pain, likely secondary to chemical arachnoiditis." MRI of her

lumbar spine showed "debris in the caudal aspect of the thecal cell, probably … blood or pus within this debris … suggest[ing] arachnoiditis." It was noted that she had recently had an epidural injection and a block for her back pain. Plaintiff also had an MRI of her brain. Infectious Disease was consulted. She was believed to be suffering from chemical arachnoiditis and was treated with IV steroids and high doses of narcotic pain medication.

204. On September 23, 2012, Plaintiff was discharged from Franklin Square to home with Dilaudid for pain and steroid medication.

205. On September 27, 2012, Plaintiff returned to Box Hill Surgery Center. Dr. Bhambhani noted her prior hospital admissions and diagnoses of aseptic meningitis and arachnoiditis. She also noted that Plaintiff was taking Dilaudid 2 mg every 4 hours, was on a tapering dose of steroids and that she still had a lot of weakness and episodes of increased pain. In addition, Dr. Bhambhani noted that she described her pain as aching and throbbing in her low back and rated her pain at 7 on a scale of 1-10.

206. On October 5, 2012, Plaintiff was re-admitted to Franklin Square. Her Infectious Disease physician noted that she personally had received an e-mail notification from the Health Department on a cluster of cases of meningitis associated with epidural injections. She called the Plaintiff to see how she was doing and was informed that she felt miserable with severe headaches, back pain, as well as new cough, chest tightness, shortness of breath, oral ulcers and difficulty swallowing. She advised Plaintiff to go immediately to the ER so she could have a repeat lumbar puncture to check for the possibility of fungal meningitis and so that antifungal therapy could be initiated. The Infectious Disease doctor's note also stated that Plaintiff had been contacted by Dr. Bhambhani and told that she had been injected with potentially contaminated Solu-Medrol (i.e. MPA). Additional testing was ordered, including a MRI of the

lumbar spine and brain to rule out abscess. Plaintiff was admitted to a Telemetry Unit because of her chest tightness.

207. On October 8, 2012, a letter was sent to Plaintiff by Dr. Bhambhani referencing her July 13, 2012 injection and advising her that patients who had procedures between July 1, 2012 and September 18, 2012, at a Tennessee ambulatory surgery center, had developed meningitis, one patient's meningitis being due to *Aspergillus*, a mold. The letter advised that if she developed any of a list of symptoms of meningitis that she should seek immediate evaluation and let a physician know about the investigation and the concern for possible *Aspergillus* mold infection.

208. Plaintiff remained hospitalized forty-six (46) days. During this admission she was administered dual antifungal therapy. She was closely followed by the Infectious Disease team who discussed her case with the Centers for Disease Control (CDC) and the Health Department. It was determined that she met the criteria for case disposition for suspected fungal meningitis. An intravenous catheter was placed to administer antifungal medications and liver function and kidney tests were routinely done. Plaintiff suffered with hallucinations and went into renal failure from the antifungal medication. In addition, Plaintiff became depressed and frustrated with the investigations and unknown diagnoses. Psychiatry was consulted but Plaintiff did not want to take antipsychotic medication at that time.

209. On October 17, 2012, Plaintiff's renal function worsened and her nephrologist recommended avoiding all nephrotoxic drugs. This was discussed with Plaintiff's Infectious Disease physician, who, given the risks versus benefits, discontinued one of the antifungal medications, but after consulting with the CDC, whose guidelines preferred treatment over no

treatment, made the decision to continue the other antifungal medication because Plaintiff was still symptomatic, but to transition to giving it orally with frequent liver function testing.

210. On October 19, 2012, a repeat lumbar puncture was done. The opening pressure was high at 42. Plaintiff's Infectious Disease physician was concerned. Because Plaintiff remained frustrated with the fact that her headaches continued, she was offered a transfer to another hospital and she agreed that she would like to be transferred to hospital #3, Johns Hopkins Hospital (hereinafter "Johns Hopkins").

211. On October 21, 2012, Plaintiff was transferred to Johns Hopkins, where she remained for approximately thirty (30) days. During her admission she suffered relapses, received frequent spinal taps and continued to suffer from complications related to her meningitis and antifungal medication.

212. On October 31, 2012, Plaintiff advised Counsel that due to her renal failure, she had gained seventy five (75) pounds of fluid. She also advised that the blood vessels in both her eyes had ruptured and that her physicians were not sure why.

213. On November 20, 2012, Plaintiff was discharged from the hospital to her mother's home. She was forced to go to her mother's home because she was unable to navigate the stairs in her own home. Her discharge instructions included that she was to receive IV medication twice a day, physical therapy three times a week, an occupational therapist visit to teach her how to manage dressing herself, and a visiting nurse would come to her home weekly to draw blood to evaluate her kidney and liver functions.

214. On December 11, 2012, Plaintiff was very distraught. She advised Counsel that her body was still retaining approximately twenty pounds of fluid and that the skin on her legs was black and the texture of snake skin. She expressed anguish that she had no income and no

long term care insurance. She was also concerned about loosing her job because of her extended illness. Plaintiff stated she was receiving many bills that she was unable to pay and that her creditors were either lowering her credit limits or cancelling her cards.

215. On February 8, 2013, Plaintiff was still living at her mother's home because she was unable to navigate stairs. She required physical therapy three times a week and blood testing every two weeks. She was still unable to ambulate without the use of a walker and required a wheelchair when she went out. She was unable to stand to cook or clean and needed assistance with dressing and hygiene after toileting. She was taking antifungal medication twice a day and had been told that she may have to take the medication for the rest of her life. The side effects she continued to experience from the meningitis and antifungal medication included: liver toxicity, hallucinations, hair loss, confusion, constant ringing in her ears, vision problems, numbness in her feet, cellulitis in both legs, excessive tearing from both eyes, extreme pain in her arms and legs, memory loss, and bumps on her forehead, face and nose.

216. On March 11, 2013, Plaintiff was admitted to Johns Hopkins Bayview Medical Center due to severe physical deconditioning and a fall while trying to transfer in the bathroom. Multiple tests were performed including MRI of the spine, CT-guided biopsy of lumbar lesion and an EMG. Ms. Dreisch was continued on antifungal medication and was discharged to a nursing home for rehabilitation on March 15, 2013.

217. After one year, anti-fungal medication was discontinued.

218. On May 7, 2014, Plaintiff advised Counsel that she had been released from her infectious disease doctor's care. Plaintiff stated that she had no feeling from her knees down except for a feeling of tightness around her ankles. She was only able to ambulate twenty-five

steps to the bathroom holding onto her walker or the walls. She required an elevated toilet and an elevating recliner chair.

219. On June 10, 2014, Plaintiff advised Counsel that she was re-admitted to Franklin Square Hospital. She had become very sick at home with a severe headache and low back pain. A spinal tap was done and she was told the fungal infection had returned. Anti-fungal medication treatment was initiated.

220. Plaintiff and her husband have had to accept financial assistance from family members and sell personal items to pay credit card bills, medical bills and their mortgage.

221. Plaintiff will never be able to return to work and may never be able to return to her family home to live with her husband.

222. As a direct and proximate result of NECC contaminated drugs and the Defendants/Healthcare Providers wrongful conduct, Plaintiff Belinda Dreisch has suffered and will continue to suffer serious physical injuries, in addition to pain, suffering, mental anguish, fright, shock, denial of social pleasures and enjoyments, embarrassment, humiliation and mortification, emotional distress, and further has incurred and will continue to incur medical and other expenses, including loss of earning capacity as a direct result of being exposed to NECC's Contaminated Drugs.

223. Further, as a direct and proximate result of the NECC Contaminated Drugs, Plaintiff Burton Dreisch, suffered, and will continue to suffer, expenses related to the necessary medical care, treatment and services rendered to his spouse, the loss of services that he would have been provided had his spouse not been injured, and the loss of society and companionship and incidents of the marital relationship of which they have been deprived.

COUNT I
MEDICAL MALPRACTICE – NEGLIGENCE
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC)

224. Plaintiffs, Belinda L. Dreisch and Burton J. Dreisch, by their attorneys, hereby sue Defendants Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC, and state:

225. Plaintiffs incorporate by reference as if fully set forth herein, all the facts and allegations set forth in the preceding paragraphs of this Complaint and further allege as follows:

226. At all times relevant herein, the Plaintiff's physician, Defendant Ritu T. Bhambhani, M.D., was a practicing Pain Medicine specialist and the Medical Director of Defendant Box Hill Surgery Center. It is alleged that Defendants Box Hill Surgery Center, Medical Director Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC, were acting as principals/agents and/or vice versa of each other at all times relevant herein and had a relationship of principal/agent. It is alleged that this relationship existed in 2012 at the time Plaintiff's spinal steroid injections were administered by Defendant Ritu T. Bhambhani, M.D., the Medical Director of Defendant Box Hill Surgery Center.

227. The Defendants had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Plaintiff, were purchased from drug companies that complied with the laws regarding pharmaceuticals.

228. The Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Plaintiff, were purchased from a company that made safe and effective drugs.

229. The Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Plaintiff, were purchased from a company that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated.

230. The Defendants had a duty to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to Plaintiff.

231. The Defendants had a duty to provide Plaintiff with reasonable care and treatment.

232. The Defendants had a duty to obtain informed consent from Plaintiff for the procedure performed on Plaintiff, adequately and accurately describing to Plaintiff the nature of the procedure, as well as the risks of such procedure, including the drugs that were to be administered during such procedure.

233. In this case, where the drug came from an unaccredited, mass producing, out-of-state, compounding pharmacy, unregulated by the FDA, the Defendants had a duty to inform Plaintiffs of the source of the drug and the dangers associated therewith.

234. The Defendants breached their duties to Plaintiff in many respects, including, without limitation:

a. The Defendants failed to exercise reasonable and prudent care to ensure that the drugs they purchased and provided to Plaintiff were made by NECC in compliance with all applicable pharmaceutical laws;

b. The Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Plaintiffs were sold to them by NECC in compliance with all applicable pharmaceutical laws;

c. The Defendants failed to know and understand the source and supply of the drug they provided to Plaintiff;

d. The Defendants failed to use the appropriate, necessary and reasonable due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's drugs, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative free drugs for administration to Plaintiff;

e. The Defendants failed to follow the reasonable ASHP *Guidelines on Outsourcing Sterile Compounding Services*, which had they followed, would have established that NECC's products were unsuitable for administration to the Plaintiff;

f. The Defendants failed to exercise reasonable and prudent care to ensure that the drug they provided to Plaintiff was produced in sanitary, sterile conditions;

g. The Defendants failed to properly inform Plaintiff that the use of the drug was not approved by the FDA;

h. The Defendants failed to properly inform Plaintiff of the risks and dangers associated with the administration of the drug; and they failed to inform them that they had obtained the drug from NECC, a mass-producing, unaccredited, non-FDA regulated compounding pharmacy;

i. The Defendants failed to exercise reasonable care to avoid administering to Plaintiff an adulterated, contaminated and unreasonably dangerous drug;

j. The Defendants failed to conduct adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

k. The Defendants failed to visit NECC's facilities before procuring compounded drugs, and other medicines, from NECC;

l. The Defendants failed to investigate and exercise sufficient due diligence before administering drugs procured from NECC, including failing to investigate or inquire concerning NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols;

m. The Defendants failed to determine whether NECC had a history of recalling compounded medications before procuring medicines from that company;

n. The Defendants failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring drugs from NECC;

o. The Defendants failed to determine whether NECC had a history of product liability suits before procuring medicines from that company;

p. The Defendants failed to keep abreast of the dangers of sterile compounding;

q. The Defendants purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions;

r. It is believed the Defendants failed to appropriately store drugs purchased from NECC to reduce the risk of the growth of contaminants;

s. The Defendants failed to adequately supervise and train the physicians, nurses, agents and employees who ordered drugs from NECC;

t. The Defendants failed to implement policies and procedures that would prevent the procurement of purportedly sterile drugs from an out-of-state compounding pharmacy with a deplorable facility and sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

u. The Defendants administered drugs to Plaintiff without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

v. The Defendants failed to promptly notify Plaintiff that they were injected with potentially contaminated steroids and failed to recommend that they receive prompt treatment of their potential infections and other symptoms; and

w. The Defendants failed to exercise reasonable care in such other manners as may be shown through discovery and at trial.

235. The physicians, nurses, agents, employees and representatives who decided to procure drugs from NECC and who administered them to the Plaintiff were employees or agents of the Defendants, and they were acting within the course and scope of their employment or agency. Accordingly, the Defendants are liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

236. The negligence of the Defendants proximately caused Plaintiffs' injuries and distress.

237. The foregoing acts and omissions by the Defendants went beyond mere thoughtlessness, inadvertence or error of judgment.

238. The actions of the Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Plaintiff.

239. The acts and omissions of the Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Plaintiff.

240. The acts and omissions of the Defendants were a heedless and palpable violation of their legal duties respecting the life and rights of Plaintiff and therefore constitute negligence.

241. Plaintiff's injuries and distress occurred as a proximate result of the negligent acts and omissions of the Defendants.

242. Plaintiffs are entitled to recovery of damages, including punitive damages, for the unnecessary infection, emotional distress and personal injury caused by the negligent acts and omissions of the Defendants.

243. It is alleged that the Plaintiff has been rendered disabled from activities of normal living as a result of the negligence of the Defendants. She is unable to ambulate any distance without an assistive device.

244. It is alleged that in addition to the disability that the Plaintiff has suffered as a result of the negligence of these same Defendants, that the Plaintiff has incurred medical and hospital and other rehabilitation expenses, as well as lost income, and has otherwise been injured.

245. It is alleged that Plaintiff requires the assistance of friends and family for activities of daily living and will require care and assistive help in the future. The Plaintiff has suffered and will continue to suffer damages including, but not limited to, additional medical, hospital and rehabilitative expenses in the care and treatment of her condition and pain and suffering and may never ambulate unassisted again.

246. It is alleged that all of the Plaintiff's injuries and damages occurred as a direct and proximate cause of the negligence of these Defendants as described hereinabove, without any negligence on the part of the Plaintiff contributing thereto.

247. At all times material hereto, Defendants purchased, stored, handled, sold, used, administered, and/overall possessed and utilized contaminated MPA with willful and intentional disregard to the individual rights of Belinda L. Dreisch, warranting an award of punitive damaged to Ms. Dreisch.

248. Defendants represented that Plaintiff received FDA-approved Depomedrol when in fact they injected Plaintiff with NECC's compounded MPA.

249. Defendants thereby acted with oppression, fraud and malice toward Plaintiff, Belinda L. Dreisch, who requests additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in amounts sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs requests that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT II
INFORMED CONSENT
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC)

250. Plaintiff repeats herein all the above as if the same were repeated verbatim.

251. It is alleged that the Plaintiff was not afforded appropriate informed consent with respect to the risk of the procedure.

252. The Defendants provided high risk and unreasonably dangerous NECC Contaminated Drugs to patients, including Plaintiff, in the place of safe, medically acceptable drugs.

253. The Defendants failed to inform their patients, including Plaintiff, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.

254. The Defendants represented Plaintiff was receiving FDA-approved Depomedrol when in fact they injected Plaintiff with NECC's compounded MPA.

255. The Defendants prepared a Consent for Treatment Form. The form, which was presented to Plaintiff by the Defendants, and which Plaintiff read and relied upon when agreeing to accept treatment, failed to inform the Plaintiff of the risks and benefits of the procedures before it was performed. When presenting the form to Plaintiff, the Defendants knew that nobody on its behalf would be informing Plaintiff of the inferior and unreasonably dangerous nature of the NECC drug that would be administered to Plaintiff. Defendants knew that if Plaintiffs were informed of the true nature of the NECC drugs, Plaintiff would decline treatment with NECC drugs, threatening the Defendants' profits.

256. As a proximate result of the Defendants' wrongful conduct, Plaintiff suffered grievous bodily injury, has required extensive medical treatment, has incurred and in the future will incur substantial medical bills and has suffered and will in the future suffer inconvenience and severe mental anguish.

WHEREFORE, Plaintiff requests that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT III
BATTERY
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC)

257. Plaintiff repeats herein all the above as if the same were repeated verbatim.

258. As part of the medical treatment Plaintiff received at the Defendant/Healthcare Providers' facilities, their agents and/or employees purchased, prescribed and administered, via injection into Plaintiff's body, NECC Contaminated Drugs which were not sterile and which contained substances, including fungal or bacterial contamination, harmful to human life. Plaintiff was unaware of the substantial health and safety risk inherent in the use of NECC Contaminated Drugs and did not consent to the injection of contaminated drugs into her body.

259. As a direct and proximate result of Defendants' wrongful acts set forth herein, Plaintiff was injected by Defendants with NECC Contaminated Drugs, intentionally causing harmful contact with Plaintiff. As a direct and proximate result of this unwanted harmful

contact, Plaintiff suffered grievous bodily injury, has required extensive medical treatment, has incurred and in the future will incur substantial medical bills and has suffered and will in the future suffer inconvenience and severe mental anguish.

WHEREFORE, Plaintiff requests that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT IV
RESPONDEAT SUPERIOR AS TO NECC
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC)

260. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

261. At all times relevant herein, NECC was acting as an agent of the Defendants in compounding drugs to be administered to the Plaintiff by the Defendants.

262. A consensual fiduciary relationship arose when the Defendants contracted with NECC to procure compounded drugs from NECC for their patients, including Plaintiff.

263. The Defendants manifested assent for NECC to act as their agent, and on their behalf, when the Defendants contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Plaintiff.

264. NECC consented to act as the Defendants' agent, and in the Defendants' interest, when compounding, selling and delivering its compounded drugs to the Defendants, to be sold and administered to the Defendants' patients, including the Plaintiff.

265. At all times relevant herein, NECC acted within the scope of its agency with the Defendants. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.

266. The Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Plaintiff.

267. As a result, the Defendants are responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding the contaminated drugs administered to Plaintiff.

WHEREFORE, Plaintiffs requests that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT V
CIVIL CONSPIRACY
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC)

268. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

269. The Defendants acted in concert with NECC, its agents and employees, to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy patient safety requirements. Defendants accomplished that unlawful purpose via the unlawful means of using bogus patient lists to accompany orders of MPA.

270. The Defendants were involved in a conspiracy in connection

with NECC's scheme to wrongfully mislead the Massachusetts Pharmacy Board (the "Board") related to NECC's attempted compliance with the Board's rules and regulations and the Defendants willfully, intentionally, and/or recklessly participated in the conspiracy. The conspiracy resulted in NECC being able to maintain compliance with the Board's Rules and Regulations when in fact it was not in such compliance. The Board's rules and regulations are in place to ensure patient safety, and a natural and anticipated outcome from intentional and willful violation of the Board's rules and regulations would be the compromise of patient health and safety. Such Board rules include, but are not limited to, 105 CMR § 700.12.

271. The conspiracy principally involved NECC's request that the Defendants provide patient names for patients the Defendants intended to provide with MPA or other pharmaceuticals. The Defendants, however, could not provide such patient lists and NECC requested the Defendants submit any list of names to be provided to the Board. The Defendants then complied with the request by submitting a list of patients, regardless of whether those patients actually were or would be prescribed MPA or other NECC drugs.

272. The Defendants knew or reasonably should have known that patient specific names were required by virtue of the fact that NECC's standard order form for MPA and other drugs requested patient specific information. Instead of filling out these standard forms properly, the Defendants ordered NECC pharmaceuticals in bulk and thereafter submitted list of patient names, regardless of whether those patients received the ordered pharmaceuticals.

273. The Defendants were aware, or reasonably should have been aware of NECC's intent to use such patient lists in order to subvert Massachusetts Board of Pharmacy requirements.

274. Upon information and belief the Defendants had communications with NECC regarding submitting list of patient names in lieu of patient specific names to obtain bulk orders of medication.

275. NECC's customer list showed the following bulk shipments of MPA (PF) were sent to Defendants after May 21, 2012: August 13, 2012 - Eighty-five (85)- 80mg/ml injectable, 5ml; September 25, 2012 - Three hundred (300)- 80mg/ml injectable, 1ml; September 25, 2012 – Fifty (50) 40 mg/ml, 1ml.

276. The concerted action of NECC and Defendants resulted in harm to Plaintiffs.

277. The Defendants are liable for the acts of their co-conspirator NECC.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT VI
STRICT LIABILITY
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC)

278. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

279. Maryland Courts and Judicial Proceedings §5-405 (c)(1) authorize the Plaintiff, Belinda Dreisch to bring this product liability claim against Defendants Box Hill Surgery Center, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC, as the sellers of the MPA injected into Plaintiff Belinda Dreisch, because the manufacturer of the product, NECC, has filed

for bankruptcy and therefore, is not subject to service of process under the laws of this State or the Maryland Rules.

280. At the time that Defendants purchased, stored, handled, sold, used, administered and /or overall possessed and utilized MPA, it contained a defect that made it unreasonably dangerous and unfit for its intended use.

281. The product reached the Plaintiff without substantial change in the condition in which it was sold.

282. As a direct and proximate cause of this defect, the Plaintiff contracted meningitis and has suffered severe physical and emotional distress and injury; incurred medical and other expenses; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life, as more fully alleged hereinabove. The injuries and losses of the Plaintiff are permanent in nature and the Plaintiff will continue to suffer such losses in the future.

283. At all times material hereto, Defendants, who knew of should have known the damage that could occur, acted with the conscious disregard of the foreseeable harm caused by the MPA warranting an award of punitive damages to Ms. Dreisch.

284. At all times material hereto, Defendants' conduct exhibited a level of care evidencing fraud, ill-will, and such recklessness warranting an award of punitive damages to Plaintiff.

285. At all times material hereto, Defendants purchased, stored, handled, sold, used, administered, and/overall possessed and utilized contaminated MPA with willful and intentional disregard to the individual rights of Belinda L. Dreisch, warranting an award of punitive damages to Ms. Dreisch.

286. Defendants thereby acted with oppression, fraud and malice toward Belinda L. Dreisch, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example, and for the purpose of punishing Defendants for their conduct, in amounts sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT VII
NEGLIGENCE
(Against Ameridose, LLC)

287. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

288. As the designer, tester, compounder, advertiser, promoter, marketer, seller, supplier and/or distributor of consumer products, the NECC-related Defendant, Ameridose, owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care in providing a safe and quality product to the Plaintiff, i.e., MPA which was free from contamination and safe for its intended use.

289. Specifically, but without limitation:

a. Ameridose owed Plaintiff and her physician a duty to compound, and provide methylprenisolone acetate that was safe and free of contamination.

b. Ameridose owed Plaintiff and her physician a duty to provide reasonable and correct warnings, instructions and labeling to Plaintiff or her physician.

c. Ameridose owed Plaintiff and her physician a duty to properly store and ship methylprenisolone acetate.

290. The NECC-Related Defendant Ameridose breached these respective duties and was otherwise negligent in their designing, formulating, making, creating, testing, compounding, advertising, promoting, marketing, selling, supplying and/or distributing of the recalled MPA steroid medication, which was administered to Plaintiff. Defendant failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, formulator, maker, creator, tester, seller, marketer and distributor of sterile preparations and medications, as licensed to do so by the Commonwealth of Massachusetts.

291. Defendant Ameridose had an obligation and duty to exercise due care, and comply with the then existing standard of care to investigate and hire professional and competent employees to create, test, package, market and/or distribute the compounded medications and to make sure the compounded drugs being made, tested, packaged and stored did not create any harm or risk to Plaintiff and others who received the compounded medications.

292. Defendant Ameridose also had an obligation and duty to exercise due care and comply with the then existing standard of care to investigate and hire professional and competent employees or vendors to maintain NECC's production, packaging and storage facility and make sure the purported compounded sterile drugs did not create any harm or risk to Plaintiff and others who received NECC's compounded medications.

293. In breach of these duties, Ameridose failed to exercise due care and failed to supervise their respective employee(s), agent(s) or vendor(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly test the steroid medication and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding this important task and function;

b. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly compound, sterilize, package, label, store and dispense the steroid medication and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions; and/or

c. All or some of these Defendants' employee(s), agent(s) or vendor(s) failed to properly review prescriptions for NECC's compounded medications for compliance with applicable prescription laws and/or gave incorrect information or instructions on requisite prescription requirements, and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions.

d. All or some of these Defendant's employee(s), agent(s) or vendor(s) failed to properly instruct, warn or advise as to the storage, handling and pre-administration administration inspection of NECC's preservative free sterile compounded and/or gave incorrect information or instructions or warnings, and these Defendants were negligent in monitoring and supervision of their employee(s), agent(s) or vendor(s) regarding these important tasks and functions

e. These Defendants were otherwise negligent in hiring, training, and supervising their employees, agents or vendors relevant to this matter.

294. Ameridose knew, or should have known, that their respective employee or agents did not follow proper procedures and precautions and knew or should have known of the risks created by failing to do so.

295. As a direct and proximate cause of these breaches of duty Defendant Ameridose permitted the subject MPA steroid lots to become contaminated and distributed to patients throughout the United States, including Plaintiff.

296. Ameridose further breached its duties of care by failing to store, hold and compound the components of the recalled medications; by failing to properly design, compound, formulate, create, make, test, sell and/or distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain facilities where sterile medications were compounded, packaged or stored in a clean, sanitary manner, or taking reasonable steps and measures to assure these functions were performed in clean, sanitary and sterile facilities; by failing to oversee the security and quality control of NECC's or their compounding and distribution facilities; and/or by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by Plaintiff and her physician.

297. Ameridose breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, formulating, making, creating, testing, marketing, distributing and/or selling preservative free MPA.

298. NECC has been declared insolvent by the Bankruptcy Court presiding over its Bankruptcy Petition and prosecution of any and all actions against it are stayed.

299. In addition to violating the laws of Massachusetts where NECC was headquartered and maintained its facility for compounding, packaging, storing and distributing contaminated and adulterated drugs which were then shipped and distributed to Maryland for

administration to patients, including Plaintiff, all or some of the NECC-Related Defendants also violated the Maryland law.

300. The negligence of Ameridose was a proximate cause of Plaintiff's injuries, harm and losses.

301. As a direct and proximate cause of the NECC Related Defendant Ameridose's joint and several acts of negligence, carelessness and recklessness, Plaintiff was exposed to fungal contaminated steroid medication on or about August 24, 2012.

302. As a direct and proximate result of negligence of Defendant identified in this Count, Plaintiff was injected with a contaminated dose of MPA and consequently suffered injuries, conscious pain and suffering, emotional distress, and economic losses as described above.

303. Defendant Ameridose's negligence caused contamination of the MPA, rendering the product defective, unfit, and/or unreasonably dangerous to end users, including Plaintiff.

304. As a direct and proximate result of Defendant's negligence, lack of care and other wrongful acts set forth herein, which caused Plaintiff to be injected with contaminated MPA, Plaintiff contracted fungal meningitis, suffered serious bodily harm, extensive pain and suffering, and emotional distress. Plaintiff also incurred financial or economic loss, including but not limited to medical and other expenses. Plaintiff was damaged in an amount to be determined at trial.

305. At all times material hereto, Defendant acted with the conscious disregard of the foreseeable harm caused by the MPA warranting an award of punitive damages to Plaintiff.

306. At all times material hereto, Defendant's conduct exhibited a level of care evidencing fraud, ill-will, and such recklessness warranting an award of punitive damages to Plaintiff.

307. At all times material hereto, Defendant compounded, prepared, designed, manufactured, produced, labeled, promoted, sold, distributed, and/or placed in the stream of commerce MPA with willful and intentional disregard to the individual rights of Plaintiff, warranting an award of punitive damages to Plaintiff.

308. Defendant thereby acted with oppression, fraud and malice toward Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example, and for the purpose of punishing Defendant for its conduct, in amounts sufficiently large to be an example to others, and to deter this Defendant and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendant Ameridose, LLC, jointly and severally with Defendant UniFirst Corporation, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries, and losses, including punitive damages, plus allowable interest and costs in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT VIII
FAILURE TO WARN
(Against Ameridose, LLC)

309. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

310. Defendant Ameridose and its once or current principals and/or employees, manufactured and sold MPA that was injected into Plaintiff.

311. The MPA manufactured and sold by Defendant Ameridose was contaminated and as such posed a substantial health and safety risk to end users, including Plaintiff.

312. As the designer, tester, compounder, advertiser, promoter, marketer, seller, supplier and/or distributor of MPA, Defendant Ameridose and its once or current principals and/or employees, knew or reasonably should have known that its MPA was contaminated. Defendant knew or reasonably should have known of the substantial health and safety risk its product posed to end users, including Plaintiff.

313. Plaintiff was reasonably unaware of the substantial health and safety risk inherent in the use of contaminated MPA manufactured and distributed by Defendant.

314. Defendant Ameridose and its once or current principals and/or employees, failed to exercise reasonable care to warn consumers, including Plaintiff, of the substantial health and safety risk inherent in the use of its MPA.

315. As a direct and proximate result of Defendant's failure to warn Plaintiff of the health and safety risk, and other wrongful acts set forth herein, which caused Plaintiff to be injected with contaminated MPA, Plaintiff contracted fungal meningitis suffered serious bodily harm and emotional distress. Plaintiff also incurred financial or economic loss, including but not limited to medical and other expenses. Plaintiff was damaged in an amount to be determined at trial.

WHEREFORE, Plaintiffs request that judgment be entered against Defendant Ameridose for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries, losses, for punitive damages, plus allowable interest and costs in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT IX

STRICT LIABILITY
(Against Ameridose, LLC)

316. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

317. At the time that Defendant Ameridose and its once or current principals and/or employees, designed, prepared, tested, compounded, manufactured, produced, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or placed in the stream of commerce the MPA that was injected into Plaintiff, it contained a defect that made it unreasonably dangerous and unfit for its intended use, for which they are strictly liable.

318. The MPA was:

a. Defectively compounded;

b. Defectively prepared;

c. Defectively designed;

d. Defectively manufactured;

e. Defectively produced;

f. Defectively sold;

g. Defectively distributed;

h. Not safe for its intended use;

i. Contaminated;

j. Lacked adequate sterility testing;

k. Lacked proper and necessary safeguards to ensure that it was not contaminated;

l. Did not contain sufficient, adequate warnings to advise users and individuals to whom the product would be administered that the product was not tested for sterility;

m. Did not contain sufficient, adequate warnings to advise users and individuals to whom the product would be administered that the product was defective and unreasonably dangerous by nature and warn of the dangers of using and administering the product for surgical injections; and,

n. Was defective and unreasonably dangerous and caused and created an unreasonably dangerous condition and threat to persons.

319. Defendant Ameridose and its once or current principals and/or employees, placed the MPA in the stream of commerce knowing and expecting, and/or with reason to know that the MPA solution which they designed, prepared, tested, compounded, manufactured, produced, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or placed in the stream of commerce, if contaminated, would create an unreasonably dangerous and defective condition.

320. The product reached the Plaintiff without substantial change in the condition in which it was sold.

321. As a direct and proximate cause of this defect, the Plaintiff suffered severe physical and emotional distress, injury, shame, humiliation, and incurred medical and other expenses, as more fully alleged hereinabove. The injuries and losses of the Plaintiff are permanent in nature.

322. The unreasonably dangerous condition created by the MPA solution, which rendered it unsafe, and unfit, and unreasonably dangerous was known to and/or should have been anticipated by Defendant Ameridose and its once or current principals and/or employees.

323. As a direct and proximate result of the conduct of Defendant Ameridose and its once or current principles and/or employees, for which they are strictly liable, Plaintiff, suffered severe physical and emotional distress and injury; incurred medical and other expenses; and suffered shame and humiliation as more fully alleged hereinabove. The injuries and losses of the Plaintiff are permanent in nature.

324. At all times material hereto, Defendant Ameridose acted with the conscious disregard of the foreseeable harm caused by the MPA warranting an award of punitive damages to Plaintiff.

325. At all times material hereto, Defendant Ameridose's conduct exhibited a level of care evidencing fraud, ill-will, and such recklessness warranting an award of punitive damages to Plaintiff.

326. At all times material hereto, Defendant Ameridose designed, prepared, tested, compounded, manufactured, produced, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or placed in the stream of commerce MPA with willful and intentional disregard to the individual rights of Plaintiff, warranting an award of punitive damages to Plaintiff.

327. Defendant thereby acted with oppression, fraud and malice toward Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example, and for the purpose of punishing Defendant for its conduct, in amounts sufficiently large to be an example to others, and to deter this Defendant and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendant Ameridose for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries, losses, and death, for all damages allowed by Maryland law, including

punitive damages, plus allowable interest and costs in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT X
BREACH OF EXPRESS AND IMPLIED WARRANY
(Against Ameridose, LLC)

328. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

329. At all relevant times to this Compliant, Defendant Ameridose and its once or current principals and/or employees, warranted, both expressly and impliedly that the MPA solution, which was manufactured and sold to be used at locations, clinical settings, medical institutions and centers where Plaintiff and other humans were foreseeably known to use this product or to be administered this product, was of merchantable quality, and the product was fit, safe and in proper condition for the ordinary use for which it was sold, designed, manufactured, and/or used in reasonable reliance upon such warranties of merchantability, consumers and users of the MPA such as Box Hill Surgery, Dr. Bhambhani and the Plaintiff, used and/or was administered MPA solution, believing that this could be done safely and without risk of injury. The Plaintiff by the use of her reasonable care, could not have discovered the breached warranty and realized its danger.

330. The MPA solution that was sold, distributed and/or utilized during Plaintiff's spinal injection was not of merchantable quality and/or for use, but rather was unfit, unsafe and was dangerous in the manner and for the use intended by exposing users, patients, and the Plaintiff to fungus that resulted in her developing fungal meningitis which led to her serious injuries.

331. Defendant Ameridose and its once or current principals and/or employees, knew and/or had reason to know that the MPA solution was unsafe and potentially could expose

persons using the product and/or to whom the product was administered to risk of injury, including fungal meningitis.

332. The unfit and unsafe condition of the product constituted a breach of warranties of merchantability and fitness for a particular use and the breaches were the proximate cause of the injuries, harm and damages, including, but not limited to medical expenses, lost income and pain and suffering of Plaintiff.

333. At all times material hereto, Defendant Ameridose acted with the conscious disregard of the foreseeable harm caused by the MPA warranting an award of punitive damages to Plaintiffs.

334. At all times material hereto, Defendant's conduct exhibited a level of care evidencing fraud, ill-will, and such recklessness warranting an award of punitive damages to Plaintiffs.

335. At all times material hereto, Defendant Ameridose designed, prepared, tested, compounded, manufactured, produced, labeled, advertised, promoted, marketed, sold, supplied, distributed, and/or placed in the stream of commerce MPA with willful and intentional disregard to the individual rights of Plaintiffs, warranting an award of punitive damages to Plaintiffs.

336. Defendant thereby acted with oppression, fraud and malice toward Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example, and for the purpose of punishing Defendant for its conduct, in amounts sufficiently large to be an example to others, and to deter this Defendant and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendant Ameridose for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00)

for Plaintiff's injuries, losses, and for all damages allowed by Maryland law, including allowable interest and costs in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT XI
VIOLATION OF MARLAND AND MASSACHUSETTS STATE CONSUMER PROTECTION STATUTES
(Against Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC, and Ameridose)

337. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

338. The Defendants engaged in trade and commerce within the State of Maryland and the Commonwealth of Massachusetts.

339. The Defendants had a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and sale of the NECC Contaminated Drugs.

340. As described herein, Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC obtained office supplies of preservative free MPA drugs from NECC in violation of Massachusetts' controlled substances and pharmacy laws and regulations. Defendants also violated Maryland's and Massachusetts' respective consumer protection statutes.

341. As described herein, Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC presented that the medication being administered had characteristics, uses and benefits that they did not have.

342. As described herein, Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC represented that their products were of a particular standard, origin, manufacturer, quality and grade that they either knew or should have known was not of the standard, origin, manufacturer, quality or grade described.

343. Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC failed to provide accurate disclosures of all material information before Plaintiff agreed to be injected with an NECC contaminated drug.

344. Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC represented to patients, including Plaintiff and her medical benefits provider, that they were being administered or had been administered FDA-approved Depo-Medrol when in fact they injected patients, including Plaintiff, with NECC's compounded MPA.

345. Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.

346. The conduct and omission of the other pertinent parties identified above, including Ameridose and UniFirst, constituted unfair and deceptive acts and practices under Maryland and Massachusetts laws, including, but not limited to, all or some of the following:

a. Misrepresenting the nature, quality, and characteristics about NECC's compounded MPA;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety and the dispensing of pharmaceutical products;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair, fraudulent and deceptive acts set forth herein.

347. Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC's acts and omission alleged herein aided and abetted the wrongful and tortious

conduct and activities of these identified other pertinent parties, and/or served to further the conspiracy alleged herein that Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC were parties to, while at the same time, and under false pretenses, allowed Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC to obtain money from Plaintiff and/or her medical care benefit providers for NECC's contaminated drugs that would not have been paid had Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC not engaged in unfair and deceptive conduct.

348. Had Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for NECC's contaminated MPA, and would not have incurred related medical costs to address the injuries caused by the contaminated MPA.

349. Box Hill Surgery Center, Ritu T. Bhambhani, M.D. and Ritu T. Bhambhani, M.D., LLC's acts, omissions, and civil conspiracy alleged herein constitute unfair competition, unfair or deceptive acts or practices, and/or false representations in violation of Maryland's and Massachusetts' respective consumer protection statutes.

350. Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of Maryland's and Massachusetts' consumer protection statutes set forth herein.

351. Defendants actively, knowingly, and deceptively concealed the MPA product's dangerous properties and life-threatening risks of which they knew or should have known. This conduct evidences bad faith and unfair and deceptive practices.

352. The Defendants engaged in conduct as described herein that created a likelihood of confusion and misunderstanding.

353. The Defendants' conduct, aid and conspiratorial actions, as described herein, created a likelihood of causing injury to unknowing consumers, including Plaintiff.

354. The Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the products they sold and administered to Plaintiff;

b. Unfairly and improperly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiff, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

355. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally the Defendants were unethical and unscrupulous, and caused substantial injury to consumers. Defendants engaged in unconscionable actions and courses of action.

356. The Defendants willfully engaged in the conduct described herein, which they knew was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.

357. The Defendants are liable to Plaintiff and Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

358. Plaintiff was injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

359. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have allowed for the administration of NECC Contaminated Drugs, and would not have sustained injury, and incurred related medical costs and other additional financial loss.

360. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the following state consumer protection statutes, as listed below.

- Md. Code Ann., Com. Law §§ 13-101 et seq.;
- Mass. Gen. Laws Ann. Ch. 93A et seq.;

361. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and sale of the NECC contaminated drugs.

362. The Defendants are suppliers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

363. The Defendants violated the statutes that were enacted in Maryland and Massachusetts to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the

NECC MPA drug was fit to be used for the purpose for which it was intended, when, in fact, it was defective and dangerous, and by other acts alleged herein.

364. The actions and omissions of the Defendant alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

365. Plaintiff relied upon the Defendants' misrepresentations and omissions in determining which product to be administered to her.

366. By reason of the unlawful acts engaged in by the Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

367. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff and her immediate family members sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

368. Pre-suit notice of this claim is not required. The NECC Related Parties in the NECC MDL proceedings, *In Re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419 , Dkt. No. 1:13-md-2419 (FDS) (D. Mass)), have agreed to waive pre-suit notice requirements, including MGL c. 93A's pre-suit demand requirement. The waiver is documented in Case Management Order No. 6 entered in MDL No. 2419 on June 28, 2013. ARL, and Box Hill Surgery Center and Ritu T. Bhambhani do not maintain a place of business or keep assets within the Commonwealth of Massachusetts thus negating the pre-suit notice requirement under Chapter 93A.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries, losses, and for all damages allowed by Maryland law, including punitive damages; reasonable attorney's fees; and allowable interest and costs in an amount to be determined by the Court; and for such further relief as the Court deems just and proper.

COUNT XII
NEGLIGENCE
(Against UniFirst Corporation)

369. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

370. UniFirst owed Plaintiff a duty to exercise reasonable care to follow all applicable laws and standards, as well as NECC standard procedures, during the ongoing and regular maintenance and cleaning of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

371. UniFirst knew or should have known that products produced, sold, and shipped by NECC required a sterile environment, and that such products would be used by end consumers such as Plaintiff. UniFirst knew that end consumers of NECC products were the intended beneficiaries of the services to be rendered by UniFirst to NECC. UniFirst's knew that customers of a business like NECC expect and rely upon a clean and a safe environment for the production of goods. UniFirst knew this for nearly four years before the recall of the NECC Contaminated Drugs.

372. UniFirst failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a. UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the Cleanrooms (including the anterooms) in street clothes, without donning sterile or contaminant-free clothing such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities, thereby failing to follow its own standards and policies;

b. UniFirst employees, contractors and/or representatives brought into the NECC anterooms and Cleanrooms cleaning equipment, including mops, mop heads, spongers, and buckets that had been moved through exterior environments, even though such equipment had not been sanitized or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility, such actions failing to meet UniFirst's own standards as well as recognized industry standards;

c. UniFirst employees, contractors and/or representatives failed to clean or wipe footwear on mats used in the cleanroom entry process, thereby allowing contaminants into and throughout the Cleanrooms; and

d. UniFirst employees, agents, contractors and/or representatives were negligently supervised, and failed to adhere to and follow NECC standard operating procedures.

373. Each Plaintiff was a foreseeable victim of UniFirst's negligence. UniFirst knew that the Affiliated Defendants were compounding drugs at their facility for national distribution and for use in patients such as Plaintiff.

374. The wrongful conduct and negligence of UniFirst resulted in Plaintiff suffering serious physical injuries, emotional distress and pecuniary loss.

375. As a direct and proximate result of UniFirst's negligence, as well as that of UniFirst's employees, agents, independent contractors, businesses, or others associated with and/or providing services, Plaintiffs' are entitled to recover all allowable elements of damage from UniFirst in an amount that is just and appropriate to fully compensate Plaintiff for her serious physical injuries, financial loss, plus interest and costs.

376. UniFirst's conduct set out above constitutes intentional and conscious disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, Plaintiffs request that judgment be entered against the Defendant UniFirst Corporation, jointly and severally with Defendant Ameridose, LLC, for compensatory damages in excess of Seventy Five Thousand Dollars ($75,000.00) for Plaintiff's injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

COUNT XIII
LOSS OF CONSORTIUM
(Against All Defendants)

377. Plaintiffs repeat herein all the above as if the same were repeated verbatim.

378. Belinda L. Dreisch and Burton J. Dreisch were married on or about August 24, 1980. They were husband and wife at the time of the occurrence referred to in this Complaint. They continue to be husband and wife.

379. The conduct of Defendants, set forth in paragraphs 1 through 376 above, caused injury to the marital relationship of Plaintiffs Belinda L. Dreisch and Burton J. Dreisch, including loss of society, affection, assistance, companionship and sexual relations.

WHEREFORE, Plaintiffs request that judgment be entered against all the Defendants, jointly and severally, for compensatory damages in excess of Seventy Five Thousand Dollars

($75,000.00) for Plaintiffs' injuries and losses, for punitive damages, plus allowable interest, cost and expenses in an amount to be determined by the Court, and for such further relief as the Court deems just and proper.

This the 27TH day of AUGUST, 2014.

Respectfully submitted,

Sharon L Houston

Peter G. Angelos
Patricia J. Kasputys
Sharon L. Houston
LAW OFFICES OF PETER G. ANGELOS, P.C.
100 North Charles Street, 22nd Floor
Baltimore, MD 21201
(410) 649-2000
Attorneys for Plaintiffs

BELINDA L. DREISCH and
BURTON J. DREISCH
2605 Greenspring Avenue
Joppa, MD 21085

Plaintiffs

v.

BOX HILL SURGERY CENTER, LLC
100 Walter Ward Blvd.
Suite B2
Abingdon, MD 21009

Serve on:
L. Stephen Hess, Esq.
26th Floor
2100 East Pratt St.
Baltimore, MD 21202

and

RITU T. BHAMBHANI, M.D.
496 Rutland Dr.
Fallston, MD 21047

Serve on:
Ritu T. Bhambhani, M.D.
496 Rutland Dr.
Fallston, MD 21047

and

RITU T. BHAMBHANI, M.D., LLC
496 Rutland Dr.
Fallston, MD 21047

Serve On:
Resident Agent:
Ritu T. Bhambhani, M.D.
496 Rutland Dr.
Fallston, MD 21047

and

AMERIDOSE, LLC

*

IN THE

*

CIRCUIT COURT

*

OF MARYLAND

*

FOR BALTIMORE COUNTY

*

CASE NO: _____

*

205 Flanders Road *
Westborough, MA 01581 *
*
Serve on: *
Registered Agent *
Gregory Conigliaro *
205 Flanders Road *
Westborough, MA 01581 *
*
and *
*
UNIFIRST CORPORATION, *
15 Olympia Avenue *
Woburn, MA 01801 *
*
Serve on: *
Registered Agent *
The Prentice-Hall Corporation System, M *
7 Saint Paul Street, Suite 1660 *
Baltimore, MD 21202 *
*
Defendants *

* *

DEMAND FOR JURY TRIAL

The Plaintiffs demand a jury trial.

Sharon L. Houston

Peter G. Angelos
Patricia J. Kasputys
Sharon L. Houston
LAW OFFICES OF PETER G. ANGELOS, PC
100 North Charles Street
22nd Floor
Baltimore, MD 21201
(410) 649-2000

Attorneys for the Plaintiffs

BELINDA L. DREISCH and BURTON J. DREISCH 2605 Greenspring Avenue Joppa, MD 21085 Claimants v. BOX HILL SURGERY CENTER, LLC 100 Walter Ward Blvd. Suite B2 Abingdon, MD 21009 <u>Serve on</u>: L. Stephen Hess, Esq. 26th Floor 2100 East Pratt St. Baltimore, MD 21202 and RITU T. BHAMBHANI, M.D. 496 Rutland Dr. Fallston, MD 21047 <u>Serve on</u>: Ritu T. Bhambhani, M.D 496 Rutland Dr. Fallston, MD 21047 and RITU T. BHAMBHANI, M.D., LLC 496 Rutland Dr. Fallston, MD 21047 <u>Serve On</u>: Resident Agent: Ritu T. Bhambhani, M.D. 496 Rutland Dr. Fallston, MD 21047 Defendant Healthcare Providers	* *	IN THE HEALTH CARE ALTERNATIVE DISPUTE RESOLUTION OFFICE OF MARYLAND HCA No: 2014.387

ORDER WAIVING ARBITRATION AND TRANSFER

The Claimants, Belinda L. Dreisch and Burton J. Dreisch, having elected a Waiver of Arbitration under the provisions of Annotated Code of Maryland, Courts and Judicial Proceedings Art., § 3-2A-06B, it is this 20th day of August, 2014, by the Health Care Alternative Dispute Resolution Office,

ORDERED, this case shall be and is hereby, transferred to the Circuit Court of Maryland for Baltimore County.

HARRY L. CHASE, DIRECTOR
Health Care Alternative Dispute Resolution Office

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that copies of the above ORDER have been mailed, postage prepaid, to all parties of record.

Harry L. Chase, Director

BELINDA L. DREISCH and **MURTON J. DREISCH** **2605 Greenspring Avenue** **Joppa, MD 21085** **Claimants.** **v.** **BOX HILL SURGERY CENTER, LLC** **100 Walter Ward Blvd.** **Suite B2** **Abingdon, MD 21009** **Serve on:** **L. Stephen Hess, Esq.** **26th Floor** **2100 East Pratt St.** **Baltimore, MD 21202** **and** **RITU T. BHAMBHANI, M.D.** **496 Rutland Dr.** **Fallston, MD 21047** **Serve on:** **Ritu T. Bhambhani, M.D.** **496 Rutland Dr.** **Fallston, MD 21047** **and** **RITU T. BHAMBHANI, M.D., LLC** **496 Rutland Dr.** **Fallston, MD 21047** **Serve On:** **Resident Agent:** **Ritu T. Bhambhani, M.D.** **496 Rutland Dr.** **Fallston, MD 21047** **Defendant Healthcare Providers.**	* *	**IN THE** **HEALTH CARE** **ALTERNATIVE DISPUTE** **RESOLUTION OFFICE** **OF MARYLAND** **HCA No: __________________**

* *

CERTIFICATE OF QUALIFIED EXPERT

1. I, Lloyd R. Saberski, M.D., am competent to testify.

2. I have reviewed the medical records of Belinda L. Dreisch concerning care rendered by Ritu T. Bhambhani, M.D., and Box Hill Surgery Center, L.L.C., and have determined that the care of Belinda L. Dreisch represents departures from the standard of care for reasonably competent practitioners in their class and that such departures proximately caused damages to Belinda L. Dreisch (departures and damages described in attached report).

3. I further certify that I have had clinical experience, provided consultation relating to clinical practice, and/or taught medicine in the field of Pain Management or a related field of healthcare, within five (5) years of the date of the above-identified acts or omissions giving rise to this claim.

4. I further certify that I am Board-Certified in Pain Management and/or a related specialty, and/or have taught medicine in that specialty or a related field of health care.

5. I do not devote more than twenty percent (20%) of my annual professional activities to activities that directly involve testimony in personal injury claims.

Lloyd R. Saberski, M.D.

ADVANCED DIAGNOSTIC PAIN TREATMENT CENTERS, P.C.

One Long Wharf
Suite 212
New Haven, CT 06511

Phone (203) 624-4208
Fax (203) 624-4301

Steven Levin, MD
Dwight Ligham, MD
Lloyd Saberski, MD
Michael J. Robbins, DO

May 18, 2014

Attorney Sharon L. Houston
Law Offices of Peter G. Angelos, P.C.
One Charles Center
100 N. Charles Street
Baltimore, MD 21201

Direct Line 410-649-8839
Toll Free 800-252-6622
Fax 410-649-2101
Email: SHouston@lawpga.com

Re: Ms. Belinda Dreisch

Dear Attorney Sharon L. Houston:

I, Lloyd Saberski, Board Certified in internal medicine, anesthesiology, and pain management with an unrestricted license to practice medicine in the State of Connecticut, had an opportunity to review the medical records of Belinda Dreisch and form opinions. The medical records reviewed were:

1. The medical records of Ritu Bhambhani, MD & Box Hill Surgery Center
2. Upper Chesapeake Medical Center , Admission 09-12-12, ER 09-15-12
3. Franklin Square Hospital, Admissions 09-17-12, 10-05-12
4. Johns Hopkins Hospital, Admission 10-20-12
5. Johns Hopkins Hospital Clinic Notes – Dr Seema Nayak

Ms. Belinda Dreisch was a 54-year-old woman; evaluated September 19, 2011 for low back and right leg pain by Dr. Ritu Bhambhani; diagnosed low back and right leg pain secondary to lumbar degenerative disc disease, lumbar spondylosis, L4 & L5 lumbar radiculopathy / radiculitis with a possibility of some irritation of the S1 nerve root. A recommendation made for right L4 and L5 selective nerve root blocks. If ineffective, indicated consideration of L34, L45, L5S1 facet medial branch nerve blocks or a caudal epidural steroid injection.

Ms. Belinda Dreisch went on to have a series of injections at the the Box Hill Surgery Center including September 23, 2011, May 18, 2012 and July 13, 2012 for the right L4 and L5 selective nerve root blocks all performed without known immediate complication;

a total of 80 mg of Depo-Medrol injected for each procedure yielding a total Depo-Medrol dose of 240 mg. Ms. Dreisch also had a caudal epidural performed August 24, 2012 with an additional 80 mf Depo-Medrol.

By September 11, 2012 Ms. Dreisch was diagnosed with aseptic meningitis and hospitalized until September 23, 2012. She however, continued to feel ill requiring multiple evaluations and hospital admissions. Infectious disease specialist Dr Nayak Seema documented November 28, 2012, presumptive fungal meningitis secondary to tainted epidural steroid injections and treated for the same. In follow up October 23, 2012, Dr Seema reported she has a history of fungal meningitis after steroid injections and continues to have side effects from her anti-fungal therapy.

Discussion: Therapeutic steroid injections have been utilized in medicine routinely for years, including spinal injections with corticosteroids. The standard of care requires that any injectable substance that a physician utilizes is safe, sterile, and prepared to accepted industry standards. Steroids utilized for injection are commercially available from various manufacturers and meet Federal Drug Administration requirements.

In the case of Belinda Dreisch, the steroids used were from NECC, a compounding pharmacy that manufactured methylprednisolone acetate without preservative in multidose vials. Through investigation, it has been found that compounded methylprednisolone at NECC were contaminated with various organisms, including fungi. Regrettably, the presence of contaminants, including fungi, when injected into susceptible patients like Belinda Dreisch, caused life-threatening infections.

Conclusions: Based on my review of the above materials and my knowledge, training, and experience, it is my opinion, with reasonable medical probability or certainty, that healthcare provider Dr Bhambhani was negligent and violated acceptable standards of care by:

1. Failing to exercise reasonable and prudent care to ensure that the steroid preparations used for injections were sterile, free of contaminants, and compounded in accordance with all applicable industry standards.

2. Failing to exercise real and prudent care to ensure that the drugs purchased for therapeutic injections into Belinda Dreisch were purchased from a drug manufacturer or compounder that reliably and consistently utilized proper quality control, safety, and sterility measures so as to minimize or eliminate the possibility that the drugs were not sterile or contaminated.

3. Failing to exercise reasonable care to avoid injecting Belinda Dreisch with contaminated drug.

4. Failing to purchase and administer a steroid preparation with a preservative, such as Depo-Medrol for therapeutic injections, as opposed to injecting Belinda Dreisch with preservative-free methylprednisolone.

5. Failing to properly inform Belinda Dreisch that the steroid medication she was administered was not the Federal Drug Administration approved drug Depo-Medrol but, rather, was a non-Federal Drug Administration-approved formula, namely, preservative-free methylprednisolone acetate.

6. Failing to warn Belinda Dreisch of the risks and dangers associated with the injection of preservative-free steroid medication, including increased risk of infection.

7. Negligently using preservative-free multidose vials of steroidal preparations rather than single-dose vials.

8. Falsely documenting that Depo-Medrol was the steroid used when compounded preservative-free methylprednisolone acetate utilized.

9. Failing to comply with applicable statutes, regulations or guidelines governing the prescription and dispensing of compounded prescription medication for patients

It is my opinion that as a direct and proximate result of the violations of the standard of care by Dr. Ritu Bhambhani and the Box Hill Surgery Center as described above, claimant suffered a fungal infection which has been associated with multiple complications either directly from the infection or the treatments for the infection and include but not limited to, chronic intractable pain, visual hallucinations, peripheral neuropathy with describing right leg as feeling like a "piece of wood" and ambulation only with an assistive device.

Attorney Houston, if you should have any further questions regarding my opinions, please do not hesitate to contact me.

I remain respectfully yours,

Lloyd Saberski, MD

Circuit Court for Baltimore County
City or County

CIVIL - NON-DOMESTIC CASE INFORMATION REPORT

DIRECTIONS:

Plaintiff: *This Information Report must be completed and attached to the complaint filed with the Clerk of Court unless your case is exempted from the requirement by the Chief Judge of the Court of Appeals pursuant to Rule 2-111(a).* ***A copy must be included for each defendant to be served.***

Defendant: *You must file an Information Report as required by Rule 2-323(h).*

THIS INFORMATION REPORT CANNOT BE ACCEPTED AS AN ANSWER OR RESPONSE.

FORM FILED BY: ☒ PLAINTIFF ☐ DEFENDANT CASE NUMBER _____ (Clerk to insert)

CASE NAME: Belinda L. Dreisch and Burton J. Dreisch (Plaintiff) vs. Box Hill Surgery Center, LLC, et al. (Defendant)

JURY DEMAND: ☒ Yes ☐ No Anticipated length of trial: _____ hours or 14 days

RELATED CASE PENDING? ☐ Yes ☒ No If yes, Case #(s), if known: _____

Special Requirements? ☐ Interpreter (Please attach Form CC-DC 41)

☐ ADA accommodation (Please attach Form CC-DC 49)

NATURE OF ACTION (CHECK ONE BOX)

TORTS
- ☐ Motor Tort
- ☐ Premises Liability
- ☐ Assault & Battery
- ☐ Product Liability
- ☐ Professional Malpractice
- ☐ Wrongful Death
- ☐ Business & Commercial
- ☐ Libel & Slander
- ☐ False Arrest/Imprisonment
- ☐ Nuisance
- ☐ Toxic Torts
- ☐ Fraud
- ☐ Malicious Prosecution
- ☐ Lead Paint
- ☐ Asbestos
- ☒ Other
  PRODUCT LIABILITY AND PROFESSIONAL MALPRACTICE

LABOR
- ☐ Workers' Comp.
- ☐ Wrongful Discharge
- ☐ EEO
- ☐ Other _____

CONTRACTS
- ☐ Insurance
- ☐ Confessed Judgment
- ☐ Other _____

REAL PROPERTY
- ☐ Judicial Sale
- ☐ Condemnation
- ☐ Landlord Tenant
- ☐ Other _____

OTHER
- ☐ Civil Rights
- ☐ Environmental
- ☐ ADA
- ☐ Other _____

DAMAGES/RELIEF

A. TORTS
Actual Damages
- ☐ Under $7,500
- ☐ $7,500 - $50,000
- ☐ $50,000 - $100,000
- ☐ Over $100,000
- ☐ Medical Bills $ _____
- ☐ Property Damages $ _____
- ☐ Wage Loss $ _____

B. CONTRACTS
- ☐ Under $10,000
- ☐ $10,000 - $20,000
- ☐ Over $20,0000

C. NONMONETARY
- ☐ **Declaratory Judgment**
- ☐ **Injunction**
- ☐ **Other** _____

ALTERNATIVE DISPUTE RESOLUTION INFORMATION

Is this case appropriate for referral to an ADR process under Md. Rule 17-101? (Check all that apply)

A. Mediation ☐ Yes ☐ No
B. Arbitration ☐ Yes ☐ No
C. Settlement Conference ☐ Yes ☐ No
D. Neutral Evaluation ☐ Yes ☐ No

TRACK REQUEST

With the exception of Baltimore County and Baltimore City, please fill in the estimated ***LENGTH OF TRIAL.***

THIS CASE WILL THEN BE TRACKED ACCORDINGLY.

- ☐ 1/2 day of trial or less
- ☐ 1 day of trial time
- ☐ 2 days of trial time
- ☐ 3 days of trial time
- ☐ More than 3 days of trial time

PLEASE SEE PAGE TWO OF THIS FORM FOR INSTRUCTIONS PERTAINING TO THE BUSINESS AND TECHNOLOGY CASE MANAGEMENT PROGRAM AND COMPLEX SCIENCE AND/OR MEDICAL CASE MANAGEMENT PROGRAM (ASTAR), AS WELL AS ADDITIONAL INSTRUCTIONS IF YOU ARE FILING YOUR COMPLAINT IN BALTIMORE CITY, PRINCE GEORGE'S COUNTY, OR BALTIMORE COUNTY.

Date 8/27/2014 Signature Sharon L. Hanslas

BUSINESS AND TECHNOLOGY CASE MANAGEMENT PROGRAM

For all jurisdictions, if Business and Technology track designation under Md. Rule 16-205 is requested, attach a duplicate copy of complaint and check one of the tracks below.

☐ **Expedited**
Trial within 7 months of Filing

☐ **Standard**
Trial within 18 months of Filing

☐ EMERGENCY RELIEF REQUESTED _____ Signature _____ Date

COMPLEX SCIENCE AND/OR MEDICAL CASE MANAGEMENT PROGRAM (ASTAR)

FOR PURPOSES OF POSSIBLE SPECIAL ASSIGNMENT TO AN ASTAR RESOURCE JUDGE under Md. Rule 16-202. Please check the applicable box below and attach a duplicate copy of your complaint.

☐ Expedited - Trial within 7 months of Filing ☐ Standard - Trial within 18 months of Filing

IF YOU ARE FILING YOUR COMPLAINT IN BALTIMORE CITY, PRINCE GEORGE'S COUNTY, OR BALTIMORE COUNTY PLEASE FILL OUT THE APPROPRIATE BOX BELOW.

CIRCUIT COURT FOR BALTIMORE CITY (CHECK ONLY ONE)

☐ Expedited	Trial 60 to 120 days from notice. Non-jury matters.
☐ Standard-Short	Trial 210 days.
☐ Standard	Trial 360 days.
☐ Lead Paint	Fill in: Birth Date of youngest plaintiff _____.
☐ Asbestos	Events and deadlines set by individual judge.
☐ Protracted Cases	Complex cases designated by the Administrative Judge.

CIRCUIT COURT FOR PRINCE GEORGE'S COUNTY

To assist the Court in determining the appropriate Track for this case, check one of the boxes below. This information is not an admission and may not be used for any purpose other than Track Assignment.

☐ Liability is conceded.

☐ Liability is not conceded, but is not seriously in dispute.

☐ Liability is seriously in dispute.

CIRCUIT COURT FOR BALTIMORE COUNTY	
☐ Expedited (Trial Date-90 days)	Attachment Before Judgment, Declaratory Judgment (Simple), Administrative Appeals, District Court Appeals and Jury Trial Prayers, Guardianship, Injunction, Mandamus.
☐ Standard (Trial Date-240 days)	Condemnation, Confessed Judgments (Vacated), Contract, Employment Related Cases, Fraud and Misrepresentation, International Tort, Motor Tort, Other Personal Injury, Workers' Compensation Cases.
☒ Extended Standard (Trial Date-345 days)	Asbestos, Lender Liability, Professional Malpractice, Serious Motor Tort or Personal Injury Cases (medical expenses and wage loss of $100,000, expert and out-of-state witnesses (parties), and trial of five or more days), State Insolvency.
☐ Complex (Trial Date-450 days)	Class Actions, Designated Toxic Tort, Major Construction Contracts, Major Product Liabilities, Other Complex Cases.